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UNITED STATES-CANADA OPEN BORDER AGREEMENT WITH RESPECT TO MEAT AND POULTRY

HEARING

BEFORE THE

SUBCOMMITTEE ON AGRICULTURAL RESEARCH
AND GENERAL LEGISLATION

OF THE

COMMITTEE ON AGRICULTURE,
NUTRITION, AND FORESTRY
UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

ON

PROCEDURES FOR REINSPECTION OF MEAT AND POULTRY PRODUCTS

JULY 12, 1990

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UNITED STATES-CANADA OPEN BORDER AGREEMENT WITH RESPECT TO MEAT AND POULTRY

THURSDAY, JULY 12, 1990

U.S. SENATE, SUBCOMMITTEE ON AGRICULTURAL RESEARCH AND GENERAL LEGISLATION OF THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 2 p.m., in room SR-332, Russell Senate Office Building, Hon. Thomas A. Daschle (chairman of the subcommittee) presiding.

Present or submitting a statement: Senators Leahy, Daschle, Baucus, and Bond.

Also present or submitting a statement: Senator Conrad Burns and Congressman Tim Johnson.

STATEMENT OF HON. THOMAS A. DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. The hearing will come to order. I want to thank everyone for attending this afternoon.

On February 26, U.S. Secretary of Agriculture Clayton Yeutter and Canadian Minister of Agriculture Don Mazankowski issued a joint statement announcing their agreement to conduct a 1-year experiment in which procedures for reinspection of meat and poultry products would be modified to permit products to move freely between their countries.

On June 29, the Food Safety and Inspection Service (FSIS) published a proposed rule to implement the agreement. The proposal would amend the Federal inspection regulations by exempting Canadian meat and poultry products intended for import into the United States from several requirements under these regulations, including the requirement that imported products be subject to reinspection by United States import inspectors. This means no more port-of-entry inspections of Canadian meat and poultry products by United States inspectors. The experiment will be conducted without any random or spot checks to monitor Canadian compliance with the terms of the agreement, or U.S. inspection and grading standards.

One of the responsibilities of this subcommittee is the laws governing meat and poultry product inspection. In this capacity, it is necessary to review this agreement as well as the proposed regulations to implement the agreement.

The so-called open border agreement represents a dramatic departure from current inspection procedures and holds broad implications for the meat and poultry industry and American consumers. It is significant that the agreement comes at a time, as the negotiators in the Uruguay round of the General Agreement on Tariffs and Trade consider proposals to harmonize international sanitary and phytosanitary standards.

The performance of the Department of Agriculture with respect to the negotiation and administration of this open border agreement gives us a basis on which to judge the Department's ability to handle other agreements of this kind. It also gives us a view of the changes the Department may have in mind for American consumers and the meat industry under an international agreement.

Our examination so far of the way the Department has handled the negotiation and proposed implementation of this experiment frankly has not given us confidence in the Department's ability to administer trade agreements of this kind, or of the Department's resolve in protecting the interests of U.S. processors, producers and consumers. To be successful, any free trade agreement must be based on a level playing field that treats American producers, processors and consumers the same as any other party to the agreement. Agreements based on tortured legal justifications, frankly, are just not acceptable. It is the role of the FSIS to assure American consumers that meat and poultry products, whether processed domestically or overseas, are safe and wholesome. Standards that we have established for domestic products ought to apply to foreign products. Consumers expect that meat and poultry products imported to the United States meet standards for inspection and grading that are at least as stringent as those we apply to domestic products.

Free trade must be our goal, so long as we ensure that free trade is fair trade. The question is how do we ensure that free trade in meat and poultry products is fair? Also, as we attempt to open trade in these products, how do we ensure that imported products are as safe and wholesome as U.S. products? These are two questions we hope to address at this hearing. Specifically, we intend to review these issues:

First, USDA's legal authority to negotiate and carry out this agreement, as well as the compatibility of the agreement with current statutory requirements for inspection of meat and poultry imports.

Second, the procedures USDA plans to employ to monitor and evaluate the agreement.

Third, the method USDA used to determine that Canadian inspection standards, procedures and enforcement practices are equivalent to those in the United States.

It is reasonable, and compatible with our notions of free trade, to maintain a system for monitoring industry compliance with fair and responsible health, safety and grading standards and regulations. If these trade talks were weapons negotiations, the U.S. Government would be unwilling to trust the other nation to comply with the agreement without some means to verify the other nation's compliance. We would make sure the agreement was fair and did not put our citizens at a disadvantage. We would demand and expect concessions from the other nation equal to those we offer. These principles should be understood in any trade agreement as well. American producers, processors and consumers expect nothing less.

We will insert for the record the prepared statements of Senator Leahy and Congressman Tim Johnson.

[The prepared statements of Senator Leahy and Congressman Johnson follow:]

PREPARED STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM VERMONT

I commend Senator Daschle for holding today's hearing on the proposed United States-Canada border inspection changes for meat and poultry trade.

I am gravely concerned with the administration's proposal to eliminate all U.S. inspection, including spot checks, of meat and poultry imported from Canada.

The Food Safety and Inspection Service (FSIS), USDA, has determined that the U.S. and Canadian meat inspection systems are equivalent. The General Accounting Office believes that this assessment has been insufficiently documented and based on outdated information.

Inspection of imported meat and poultry is governed by the Federal meat and poultry inspection acts. These statutes require the Secretary to perform random inspections for species verification and residues. Poultry imports must be subject to the same inspection and quality standards applied to products produced in the United States.

Regardless of the question of equivalency of the U.S. and Canadian systems, I strongly question whether any country should open its borders without spot checks on imports of meat and poultry. It is important that U.S. consumers are confident that meat and poultry sold in the United States be wholesome, unadulterated, and properly marketed, labeled and packaged.

Last month, a routine import inspection uncovered shipments of meat from Canada that were contaminated with the bacterium, *Listeria monocytogenes*. A nationwide recall of approximately 20,000 pounds of meat has been issued.

This example clearly shows how vital it is to have a minimal level of inspection on imports.

I am not saying that every shipment of meat from Canada should be fully inspected or that inspections should act as unnecessary trade distortions. There must be, however, a balance between the trade interests and the legitimate, sovereign concerns with ensuring a safe food supply.

If the administration considers spot checks on meat and poultry imports trade-distorting, I for one am ready to accept such distortion as necessary to protect U.S. citizens. Reducing trade distortion at the border does not mean that the U.S. Government should throw up its hands and walk away from that border.

In addition, I understand there may be several outstanding legal questions whether an open border system with Canada is authorized under the United States-Canada Free-Trade Agreement (FTA).

I question how far this administration is willing to go in eliminating meat and poultry inspection safeguards. The United States is supporting multilateral efforts to harmonize sanitary and phytosanitary measures on as wide a basis as possible.

These negotiations are occurring in the Uruguay round negotiations of the General Agreement on Tariffs and Trade (GATT). The GATT is comprised of almost 100 developed and developing countries. These countries have vastly different programs to protect the health and safety of their citizens.

Any agreement resulting from the GATT negotiations cannot eliminate legitimate concerns with sanitary and phytosanitary requirements. Such agreement cannot permit the administration to walk away from our borders.

PREPARED STATEMENT OF HON. TIM JOHNSON, A REPRESENTATIVE IN CONGRESS FROM SOUTH DAKOTA

I want to thank my colleague, Tom Daschle, for holding this hearing today, and I appreciate the opportunity to submit these comments for the hearing record. I have long been concerned about the impact of the United States-Canada Free-Trade Agreement on our livestock producers, and it is for this reason that I joined with Byron Dorgan to request that the General Accounting Office study concerns which had been raised about the impact of the free-trade agreement on our ability to ensure the wholesomeness of meat and poultry products being imported into this country.

I am pleased that the results of the General Accounting Office's study are available to be discussed at today's hearing, and I hope that the points that are raised by the GAO's investigation will merit consideration by my colleagues in both the House and Senate Agriculture Committees. While I do not want to impede fair trade between the United States and Canada, I am very concerned about the public's confidence in our meat and poultry supply, and the impact that any loss in that consumer confidence could have on South Dakota's beef, pork, lamb and poultry producers. A tremendous amount of effort and money have gone into establishing markets and consumer demand for these products, and as we witnessed with Alar, it does not take much effort to completely decimate such a market.

I believe that the USDA should take further steps to convince Members of Congress and the consuming public of their ability to ensure the equivalency of the Canadian meat and poultry inspection system before implementing a completely open border with our neighbors to the North. I am concerned about the findings of both the Office of Inspector General at the Department of Agriculture and with various General Accounting Office reports regarding the Food Safety and Inspection Service's inadequate documentation on equivalency between the U.S. and Canadian systems.

Again, I commend my colleague for holding this hearing and look forward to further discussion on this issue for the sake of our livestock and poultry industry and the consuming public.

Senator DASCHLE. This afternoon, we are privileged to have Jo Ann Smith, the Assistant Secretary of Marketing and Inspection Services, with us, with the Department of Agriculture. I would ask Mrs. Smith to come to the table at this time, and would invite anybody she would like to have accompany her to come as well.

Jo Ann, thank you for coming.

Mrs. SMITH. Thank you.

Senator DASCHLE. I appreciate your taking the time. I understand that you won't be able to stay for the entire hearing, but we certainly appreciate your being here for your testimony and the questions that will follow. Obviously, the entire text of your prepared statement will be made part of the record, and I would invite you to proceed in any way you see fit.

STATEMENT OF JO ANN R. SMITH, ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE; ACCOMPANIED BY DR. LESTER M. CRAWFORD, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, MARK MANIS, DIRECTOR, IMPORT INSPECTION DIVISION, FOOD SAFETY AND INSPECTION SERVICE, AND JOHN GOLDEN, REGULATORY AND MARKETING, OFFICE OF THE GENERAL COUNSEL, USDA

Mrs. SMITH. Thank you, Senator and members of the subcommittee. We appreciate the opportunity of being a part of the hearing, and certainly will cooperate in every way possible that we can to assist you and your people.

We appreciate the opportunity to testify before you today on USDA's plans for implementing the Joint United States-Canada Open Border Meat and Poultry Inspection Agreement. With me today are Dr. Lester Crawford, Administrator of the Food Safety and Inspection Service; Mr. Mark Manis, Director of the Import Inspection Division of FSIS; and Mr. John Golden, Associate General Counsel at USDA.

FURTHERS ONE OF THE GOALS

The United States-Canada open border agreement furthers one of the goals of the United States-Canada Free-Trade Agreement found in article 708(1)(d)—"to utilize each other's personnel for testing and inspection of agricultural, food, beverage, and certain related goods."

AGREEMENT IS CONSISTENT WITH SCHEDULE 10

The open border agreement is also consistent with schedule 10 of the free-trade agreement, which specifically relates to meat, poultry and egg inspection. Schedule 10 states that the United States and Canada should work toward making their inspection systems equivalent, and where those systems are equivalent, each country should accept the equivalence of the other.

STATUTORY AUTHORITY

Our direct authority for the open border agreement lies within our governing statutes, the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). In my written testimony that will be submitted, I have discussed those statutes in greater detail.

THE OPEN BORDER AGREEMENT IS ONE OF THE FIRST TESTS

The open border agreement is one of the first tests of whether the reality of the United States-Canada Free-Trade Agreement can, in fact, match the rhetoric of those who say they support free trade.

WE HAVE LONG RECOGNIZED THE EQUALITY BETWEEN THE CANADIAN AND U.S. MEAT AND POULTRY INSPECTION SYSTEMS

We have long recognized the equality between the Canadian and U.S. meat and poultry inspection systems. There is a key element of Canada's meat and poultry inspection system that makes Canada unique from all other countries, but most similar to the United States, and that is that the Canadians have only one standard of inspection. There is only one standard of inspection in the United States. Every other country in the world has one standard of inspection for products to be exported and another standard for products to be consumed domestically.

USDA AND AGRICULTURE CANADA HAVE COMPARABLE INSPECTION SYSTEMS

In addition to the one standard of inspection, USDA and Agriculture Canada have comparable inspection systems, registration, sanitation, label requirements, as well as residue testing programs. The inspection programs in both the United States and Canada are comprehensive and mandatory, and have been in existence since the early 1900's.

As you know, the U.S. Department of Agriculture and Agriculture Canada agreed in February 1990 to implement on a 1-year basis an experimental open border agreement with regard to meat and poultry trade.

INSPECTION

Pursuant to notice and comment rulemaking, Canadian products to be exported to the United States will be inspected by Agriculture Canada and certified for export. Those products may then be imported into the United States without further reinspection by USDA. The same is true for U.S. products. They will be inspected by USDA and certified for export to Canada. Agriculture Canada will not reinspect U.S. imports.

EVALUATION

An evaluation of this experiment will take place by the Meat, Poultry and Egg Inspection Working Group, which was established by the free-trade agreement. The evaluation will determine whether the open border experiment should be made permanent under the applicable law and the free-trade agreement.

OPEN BORDER AGREEMENT IS ONLY A PROPOSAL AT THIS STAGE

I do want to stress that the open border agreement is only a proposal at this stage. A great deal of time and effort has gone into the proposal, and much more will be done before a decision is made on a final rule. We have worked closely with the Canadians in developing the open border agreement. We will continue to do so if and when the agreement goes into effect.

Again, there is much more work that will be done before a final rule is issued. We will not issue a final rule until we are completely satisfied that the Canadian system provides the same food safety assurances that we have through our inspection system.

IMPORTANT WORK INVOLVES COMMENTS RECEIVED ON THE PROPOSED RULES

The most important work before the final rule will involve the comments we receive on the proposed rule. I hope each of you will encourage anyone with concerns about our proposal to provide us with their comments. I assure you that we will examine each comment carefully in order to ensure that the experiment will allow continued high standards of food safety.

Mr. Chairman, that concludes my testimony and I would be happy to respond to any questions that you or other Senators might have.

Senator DASCHLE. Thank you very much, Mrs. Smith.

Let me call on my colleague, Senator Burns, for any opening remarks that he might like to make at this time, and I welcome him to the subcommittee and appreciate his interest in the issue.

STATEMENT OF HON. CONRAD BURNS, A U.S. SENATOR FROM MONTANA

Senator BURNS. Thank you, Mr. Chairman. I have some comments.

First of all, I appreciate your calling this important hearing because it is apropos at this time, and for allowing me the opportunity just to make a statement, and maybe if I could, with your permission, ask a couple of questions later on because it seems like those of us who live in the border States, and especially from meat-producing States, have a very deep and sincere interest in this.

It seems like we get into these situations where we keep talking about trade, and trade is very important to this country, there is no doubt about it, and how we handle that trade. But sometimes we do some things in the name of trade that take precedent over other things that we think should be a lifted a little bit higher on the priority list. I don't think there is a greater charge given to the U.S. Department of Agriculture than that of food safety.

Mr. Chairman, I believe that trade must take a back seat to food safety. Other countries safeguard their borders and their food safety. The Europeans, with their beef hormone ban, come to mind, and we can do no less in this country. The food products that consumers buy must be safe. Consumer confidence in this matter is paramount. Over the past several months meat coming into this country from Canada has had some problems. There have, for instance, been at least three recalls of Canadian hot dogs in this country that have tested positive for Listeria.

The Canadian difficulties come at the same time that the Department of Agriculture is proposing to further streamline its inspection procedures in order to further the goals of the United States-Canada Free-Trade Agreement. The Department's notice of proposed rulemaking has been published. The comment period, however, is only for 30 days. I believe that it would serve the Department of Agriculture—and the public—well to extend the comment period to 60 days.

I have been working with the Department of Agriculture on this matter since it was brought to my attention last April by Clint Peck, editor of the Montana Farmer-Stockman in my State. Since that time, Mrs. Jo Ann Smith and I have had several private meetings to see if something could be done to ensure the safety of the meat coming across the border. I have also talked with Bill Lehman, the inspector in Sweetgrass, Montana, who communicated his concerns to me. In my view, there is a safety concern here.

I feel I must point out my own frustration at this point. The United States-Canada Free-Trade Agreement is probably a good thing for the country. But the Department of Agriculture must be sensitive to the impact that such a treaty has on agriculture and on the States that border Canada. My own State is a case in point. Agriculture is important to us. We raise a great deal of beef cattle and lamb, and we are very dependent on high consumer confidence in our product for our well-being. A crisis in confidence would be devastating to my own State and to the States of many others and would be particularly hard on border States—northern high plains.

The Department must take the needs of agriculture, the needs of consumers, and the needs of border States like Montana into greater consideration as it moves pell mell toward implementation of the United States-Canada Free-Trade Agreement.

Related to the issue of food safety is the point raised by the recently released General Accounting Office report that indicates that there may be statutory questions associated with this matter, allowing a less than 100 percent inspection of meat entering the United States from Canada. The report states that (page 2, GAO Report to Congressional Requesters, "Food Safety: Issues USDA

Should Address Before Ending Canadian Meat Inspections," GAO/RCED-90-176, July 6, 1990):

> The open border proposal raises both legal and policy issues. FSIS' program officials have raised a possible legal issue about whether authority exists to permanently establish an open border or whether FSIS needs to ask the Congress to amend the Federal Meat Inspection Act. From a policy perspective, FSIS needs to ensure that food safety will not be compromised under an open border system. Also, we believe the rejection rates experienced under streamlined inspection and the lack of a well documented equivalency review are concerns that FSIS should address in its decision on the proposal.

Mr. Chairman, it is in the best interests of all producers—beef, dairy, grain, fruits or vegetable, whatever it might be—here in the United States or Canada—that food safety must be our first concern here.

I thank you, Mr. Chairman, for this opportunity. I also have a statement from the Montana Meat Processors Association that I would like entered into the record.

Senator DASCHLE. Without objection, it will be made part of the record.

[The prepared statement of the Montana Meat Processors Association follows:]

PREPARED STATEMENT OF THE MONTANA MEAT PROCESSORS ASSOCIATION (MMPA), JOHN W. MUNSELL, CHAIRMAN, GOVERNMENTAL AFFAIRS COUNCIL, MONTANA MEAT PROCESSORS ASSOCIATION, DATED JULY 10, 1990

The Montana Meat Processors Association would like to express its primary commitment to the wholesomeness and sanitation of food being offered to consumers, and secondly to the removal of artificial trade barriers which prevent equitable international trade. We are adamantly opposed to sacrificing product wholesomeness to obtain free trade.

In recent months, a steady stream of accusations have emerged which indicate an abnormally high rate of product rejections at border inspection points. If these allegations are true, and official USDA documents will confirm or deny this, the entire meat industry is sitting on a *timebomb* ready to burst on the international news scene. The fuse required to detonate this scenario will be public awareness of product contamination, and/or outbreaks of sicknesses related to consumption of such products. Once this occurs, every segment of the food chain will be adversely affected because of an inevitable decline in consumer consumption of meat products. A case in point is declining consumption in England due to the "mad cow" disease. Live animal prices will fall, futures drop, processors will have less work, retailers' sales will lag, and the cholesterol scare will take a back seat to the newest government-created boon-doggle. All of these adversities can be prevented, and freer trade still accomplished, via implementation of a common-sense international trade agreement with enforceable guidelines.

The Montana Meat Processors Association suggests the following ideas be incorporated into a free-trade agreement. These ideas are not all-inclusive, but should merely be a portion of the agreement's rules and should rectify many of the inequities recently observed. These ideas would govern shipments originating in BOTH countries.

1. AFTER a shipment of meat has been loaded and is ready to move in commerce, a government official should place a government seal on the load and enter such information into a central computer bank.

2. The computer should randomly select individual truck loads which must be reinspected at border inspection points. Other loads not requiring border inspections must be allocated a clearance permit number. These trucks must still stop at customs to have their permit verified and entered in the same central computer bank. This verified and stamped permit must accompany the load of meat until the entire shipment has been unloaded. Any truck found not carrying this verified, stamped permit will be impounded and taken to the nearest facility available for reinspection. Stiff fines must be imposed for such an infraction, and even stiffer fines if the load is found to be carrying contaminated, irregular, or mismarked products. These

penalties should hold no fear for legitimate, legal operators, but will help to eliminate the illegal operators which tarnish the industry's image.

3. Initially, perhaps 1 in 15 trucks should be inspected at the border. As individual meat packers develop a good track record the frequency of border inspections will dramatically diminish. Packers with poor track records will experience an increasing frequency of border inspections which could eventually reach a 100 percent rate. This system will provide a meaningful incentive to packers to provide excellent quality control, and will justly reward the better packers for their professionalism.

4. Border inspections must include inspections of a random sample of boxes throughout the entire load, not merely a few boxes conveniently placed on the tail end of the load.

5. Border inspections are vastly superior to destination inspections since many destinations have no government inspectors assigned to them. For example, meat arriving at retail store warehouses such as Safeway, Kroger etc. will directly enter the food chain in the absence of government inspection.

6. Rejected loads must have a "Reject" seal attached, and all pertinent information must again be entered into the central computer bank. This seal can only be broken by the government inspector at the originating packing plant, who has the duty to communicate his findings to the inspector who rejected the shipment. One packer violation of this principle requires a written reprimand, and the second violation results in a 3-year ban on exports, including subsidiaries. Inspectors not complying with these rules will be terminated following their second violation of noncompliance.

The Montana Meat Processors Association is also concerned with the credibility of American exports to other foreign countries if the Canadian free-trade agreement does indeed create opportunities to ship unwholesome meat. As the European Community organizes and exercises its collective economic clout, they will turn thumbs down on products originating from any country that is currently involved in shoddy, and shady export sanitation practices. At the very least, our country will lose precious bargaining power.

Border inspections in recent months suggest that the "free-trade agreement" is a misnomer. If the product wholesomeness allegations are verifiable, the existing procedures are more aptly called the "sanitation free" trade agreement. The entire industry suffered when the Kangaroo meat fiasco hit the news media, and when the Cattle King problems surfaced in the early 80's. Let us work together to provide the consuming public a product which is consistently wholesome, and to create laws which will provide adequate disincentives to potential fraudulent packers from even considering exports. Let us handsomely reward the professional packers by making international trade easier. However, let us not throw out the baby (product quality) with the bathwater (FTA) either. Let us design the system with strong, enforceable provisions which impose fines, export bans, and/or prison terms to violators.

Senator BURNS. Thank you, Mr. Chairman, and I will have some questions later on. Thank you for your courtesy.

Senator DASCHLE. Senator Baucus.

STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA

Senator BAUCUS. Thank you, Mr. Chairman. I welcome my colleague from Montana to this committee.

Mr. Chairman, this is an issue which has raised a lot of concern in our part of the country, and I am sure in your State as well. There are a couple of very enterprising reporters in the State of Montana. One is Clint Peck with the Montana Farmer-Stockman, who has diligently looked into this issue. He asked a lot of questions of a lot of people. He has written a lot of articles, and he is to be commended for his very diligent journalistic work, very much in the public service.

I might add, Mr. Chairman, that the Montana Farmer-Stockman is not a sensational rag. It is a periodical which very much has the State and the nation's farmer and stockmen's best interests in mind. It is a journal he works for and I think he does an excellent job.

In addition, Mr. T.J. Gillis of the Great Falls Tribune has done a good job, too. He has written a lot of articles on this; he has worked hard on it. He is one of the premiere agricultural reporters in the State of Montana, and I want to compliment him.

I have spent hours talking with both of them and I think they have done a great job.

In addition, Mr. Chairman, I might add that there are legitimate concerns here. Certainly, the United States-Canada Free-Trade Agreement is one. I personally held up passage of that agreement for a long time as a member of the Senate Finance Committee. The committee has jurisdiction over the free-trade agreement, and one day I got a telephone call from then Treasury Secretary Jim Baker. He called me up and gave me an earful because I was opposing this agreement.

He asked me what I wanted in order to support it, and I told him there are two points. One of them was that Canada, I think, still excessively subsidizes its industries at the expense of the United States. And, second, the agreement did not sufficiently protect American agriculture, particularly honoring section 22 of the Agricultural Stabilization Act.

Secretary Baker asked me if I would support the agreement if the agreement made those two changes, and I said, yes, I would, and those two changes were made, the point being that I was very skeptical as to whether that agreement would sufficiently protect the interests of American agriculture.

Now, we are finding that this experimental open border policy is certainly questioning the degree to which it is in the best interests of American livestock producers, and particularly American consumers.

Now, the point of this hearing is to look into all of this to find out whether this open border meat inspection policy is or is not protecting Americans. I have a lot of questions going first to the degree to which Canada and the Canadian officials and others are adequately inspecting.

The second question goes to legality. The General Accounting Office and the congressional Research Service both believe and have concluded that this is an excessive delegation; that is, the statute delegates meat inspection to the Department, not to the country of Canada.

Most likely, in order to avoid the appearance of illegality—or not only the appearance, but the problem of illegality of the present action, the administration will have to submit for congressional approval the administration's meat inspection plan with the Government of Canada. I think probably it has to be approved by Congress before it is sufficiently legal. Certainly, in that process, the Congress will make whatever changes it deems necessary in order to adequately protect not only American stockmen, but also American consumers.

So I am very honored, Mr. Chairman, that you are holding this hearing, and I am happy that my colleague from Montana is joining us in the Agriculture Committee today for this hearing and I look forward to seeing what we can come up with.

Senator DASCHLE. Thank you, Senator Baucus.

Mrs. Smith, just to start out, I think there are three categories of concerns that I have personally, at least initially, and then there are other questions that may not fit any neat category. But the first is legal authority, the second is equivalency in inspection, and the third is the procedure we are using.

Going to the first category, that of legal authority, you made reference to it in your opening remarks, but I would like to delve into that, if I could, a little bit. Could you specifically cite that part of law which gives the Secretary the confidence that he is acting within the law to designate inspection responsibilities to personnel in a foreign government?

Mrs. SMITH. I would like to make some comment on it, and, as I indicated in my opening introductions, I have with me John Golden, Office of General Counsel, and I would like for him to further reply to the comments and clarify anything that you might pursue.

We first looked at both our authority—when I say our authority, the authority with FSIS, encompassing USDA's authority—and then whether or not through the United States-Canada Free-Trade Agreement, it was the intent, and if so, where in the agreement it rested. So those were the two areas.

I cited in my comments 708(1)(d) is, in the United States-Canada Free-Trade Agreement, the area that we feel speaks to the issue. We looked further, and section 10 is the section that is explicit as it relates to meat, poultry and eggs.

Senator DASCHLE. Why don't we just stop there? Maybe, for the record, I think we ought to make some reference to what those specific authorizations are. My interpretation is totally different than that, I must say, and I think it would be helpful for us to talk a little bit about that.

You say 708(a), is it?

Mrs. SMITH. 708(d).

Senator Daschle. (d), OK. What does 708(d) say?

Mrs. SMITH. 708(d) is the subsection in the article that is the technical regulations and standards for agricultural food, beverages and certain related goods. (d) is to establish reciprocal training programs and, where appropriate, to utilize each other's personnel for testing and inspection of agricultural food, beverages and certain related goods.

As you move to schedule 10, it talks, in part—and I will be happy to submit this to you—if I may just kind of walk through here and have the General Counsel make sure I do it correctly, it talks about how the parties shall work toward making equivalent and, where equivalent, accepting the equivalence of: each other's views of recognized meat and poultry inspection systems and facilities of third countries; each other's internal review systems with respect to meat, poultry and egg inspections; the product inspection systems; the laboratory procedures, such as whether they are federally accredited labs—it specifically states meat and poultry; and the methodology and procedures that are used.

Senator DASCHLE. But there is a big difference between saying in the case of schedule 10 that the parties shall work toward making equivalent the things you mention—specific testing methods and such—and what the Department is doing, which is a total, wholesale designation of responsibility to the Foreign Inspection Service in Canada.

Mrs. SMITH. OK. As I said, there were two areas we went to. One was the United States-Canada Free-Trade Agreement. The specifics of where it gives us the authority to do this— recognizing that Canada has an equivalent system that we feel has been monitored for years upon years—the exact authority comes from within our statutes, and I would like to ask John Golden to give you the statutes in the Meat and Poultry Act where those are, if I might.

Senator DASCHLE. OK, good. Go ahead, Mr. Golden.

Mr. GOLDEN. Thank you. Senator, we rely upon an interpretation of two sections, one in the Federal Meat Inspection Act and one in the Poultry Products Inspection Act. The section in the Meat Inspection Act is 620(f), and 466(d)(3) of the Poultry Products Inspection Act.

Those are the sections which provide for the mandatory inspection activity the Secretary must impose to assure that product brought in from foreign countries meets the various standards that those Acts require that they meet.

Senator DASCHLE. Now, let us stop there for a minute.

Mr. GOLDEN. Sure.

Senator DASCHLE. What it says—I am not a student of this particular part of law, but as I understand it, what you are saying is the law mandates that the imported product be of an equivalent quality to meet the standards set in this country. That is what the law requires, right?

Mr. GOLDEN. That is correct.

Senator DASCHLE. So, that deals with equivalency, first of all. It doesn't deal with the authority to be designated to foreign inspection agents. Is that a correct interpretation?

Mr. GOLDEN. That is correct, but the——

Senator DASCHLE. So how is it that those provisions of law can be cited as the reason for this designation?

Mr. GOLDEN. The statute says, in effect, that the foreign product has to meet the same standards as the U.S. product, and then it goes on to say that the Secretary shall enforce this provision, and there are two ways that the statute requires that he enforce those standards.

He has other discretionary authorities that he can use, of course, but the two that are required by the statute are that he shall enforce the—I will use language of the Meat Inspection Act. The Poultry Products Inspection Act language is virtually parallel; there are some differences, but they are virtually parallel.

It says that the Secretary shall enforce this provision through, one, the imposition of random inspections for such species verification and for residues.

Senator DASCHLE. But under this proposal, we have eliminated random inspections, have we not?

Mr. GOLDEN. Well, we haven't.

Senator DASCHLE. We have not eliminated random inspections of imported Canadian product?

Mr. **Golden**. That is correct. The proposed regulation would have those random inspections conducted by Canadian officials in Canada.

Senator **Daschle**. Well, we are full circle now. I mean, we say, all right, we are going to have random inspections, but the Canadians are going to conduct the random inspections. So we are designating the authority, but you say, well, the catch is there will be random inspections. The catch to having imported product inspected by foreign inspectors is that we are going to have random inspections, but the people who will do the random inspection will be the foreign inspectors. So where does the check come?

Mr. **Golden**. Well, that is not unusual because the next section of that provision goes on to require that the Secretary shall enforce the provision through random sampling and testing of internal organs and fat of the carcasses for residues at the point of slaughter by the exporting country in accordance with methods approved by the Secretary.

Senator **Daschle**. But, again, that assumes inspections will be conducted by an American inspector, does it not?

Mr. **Golden**. No, it does not, no. That would be a Canadian inspector, and the only requirement would be that when the Canadian inspector was testing internal organs and fat of the carcasses for residues at the point of slaughter, he would do so in accordance with methods approved by the Secretary.

Senator **Daschle**. But how do we know if the Canadians are in compliance or not if we never have any American verification of that inspection?

Mrs. **Smith**. I think at this point it might be a good time for Dr. Crawford, who is head of FSIS, to go back and give a little bit of history of why we feel that the system is equivalent to ours. I think it is important to build that kind of background of stability here so that you fully understand that we have almost identical types of inspections between what Canada does and what we do in every plant, such as they inspect every carcass; we inspect every carcass. All the labels have to be approved. We have to approve all the labels here.

Senator **Daschle**. The approval of labels really is nothing more than an approval of a seal that you put on, assuming all the inspection is appropriate.

Mrs. **Smith**. No, that is not really true with what we say about label approval.

Senator **Daschle**. We are going to get into equivalency in just a minute, Mrs. Smith, but before we get into equivalency, which was what I said was the second category of questions I want to ask—and we will get into that in complete detail—let me just ask some procedural questions about this particular issue because I think it sets the stage properly to go in, then, to equivalency.

Was the agreement signed by Mr. Crawford and Canadian Assistant Deputy Minister of Agriculture Dr. J.B. Morrissey submitted to or cleared by the Office of General Counsel prior to it being signed?

Mrs. **Smith**. I would like to answer that myself. There was a tentative agreement that they reached. It was assumed by some people to be something that had not been looked at. We had not formally submitted it to OGC. We looked at how we could come to an agreement. It was then submitted to OGC for their approval.

Senator **Daschle**. It was submitted, but that doesn't answer my question. Was it ever approved by OGC?

Mrs. **Smith**. Yes, it was.

Senator **Daschle**. It was approved by OGC?

Mrs. **Smith**. It was approved by OGC.

Senator **Daschle**. Could you give me some documentation for the record as to date, and just submit that formal approval?

Mrs. **Smith**. Yes, I will.

[The information referred to was subsequently supplied for the record and follows:]

Department of Agriculture,
Office of the Secretary,
Washington, DC, August 6, 1990.

The Honorable Thomas A. Daschle,
Chairman, Subcommittee on Agricultural Research and General Legislation, U.S. Senate, Washington, DC.

Dear Senator Daschle: Enclosed are the materials you requested to supplement testimony by USDA officials during the recent hearing on the Open Border Proposal by the Subcommittee on Agricultural Research and General Legislation. Following is a brief description of the materials enclosed.

The first requested submission concerns OGC consideration and approval of the Open Border Agreement. The NOTICE OF PROPOSED RULEMAKING implementing the open border experiment was approved by OGC for legal sufficiency. Earlier we had submitted the agreement signed by Dr. Crawford and Mr. Morrissey to OGC for their review. OGC advised us that implementation of the agreement could only be accomplished legally through notice and comment rulemaking. I understand you have heard directly from the Department's General Counsel on the matter of the legal memorandum, dated May 18, 1990, which also addresses this subject.[1]

The next document requested concerns the record of the meeting of February 20, 1990 that resulted in the signing of the Joint U.S.-Canada Open Border Meat and Poultry Inspection Agreement. The Agreement, which was signed by Dr. Lester Crawford and Mr. J.B. Morrissey, is the only record of that meeting, and a copy of the Agreement is enclosed.[2]

A request was also made for information on differing compound approvals or other discrepancies between the two countries' requirements. We are supplying the lists of approved animal drugs for each country.[3] However, we do not maintain an inventory of other specific additive differences. It is important to note that each processor must meet the requirements of the country to which he or she is exporting his product. That is true for additives, product standards, or any other specifications.

We are supplying a variety of documents to address the issue of documentation to support our determination of the equivalence of the Canadian inspection system. These documents include summary review reports, plant review forms, and laboratory review forms. The documents are dated 1988 because that is the last year in which we used the equivalency determination approach we use in other countries for Canada. Beginning in 1989, we changed the type and scope of our oversight activities. We are also supplying detailed material concerning the Canadian residue control program and our review of their program. We believe that these documents reflect the essential equivalence of the two inspection systems, although they are not in the format that is presently under development for use in all other countries.[3]

Finally, I want to inform you that it is our intention to reopen the comment period for an additional 30 days, as you and Senator Burns requested. We believe the comment period extension will permit full and informed consideration of this proposal.

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[1] See pp. 15-16 for letter dated July 24, 1990, from Alan Charles Raul, General Counsel.

[2] See p. 22 for this document.

[3] The documents requested are retained in the subcommittee file.

I hope this information is helpful, and I appreciate your interest.
Sincerely,

JO ANN R. SMITH,
Assistant Secretary,
Marketing and Inspection Services.

Senator DASCHLE. Did FSIS personnel discuss the proposals contained in the joint announcement or the agreement with the Office of General Counsel?

Mrs. SMITH. At various times, we discussed it with them after—I think your point is you want a timeframe here. We met and discussed what we could do and then submitted this to OGC, and pursuant to that statements were made by the Secretary and Canadian Minister of Agriculture, Don Mazankowski, but it was not made until a later date.

Senator DASCHLE. Can you elaborate a little bit as to what the context of the discussions was?

Mrs. SMITH. I think that we probably can ask Dr. Crawford to make some comment on that.

Senator DASCHLE. Let me just go back to my OGC question. Let me just say for the record, Mrs. Smith, it is my understanding OGC has not cleared it, but I am glad to see that since my understanding there has been some form of approval—I might ask, does anybody on the panel wish to elaborate with regard to that question pertaining to OGC?

[No response.]

Senator DASCHLE. There is a memo dated May 18 by OGC relating to the legal basis upon which this decision was made. Could you submit that for the record?

Mrs. SMITH. I will ask the General Counsel.

Senator DASCHLE. He is here, right?

Mr. GOLDEN. Maybe I can—there is such a memorandum, that is correct. I am not personally authorized to release a document like a legal memorandum from the Office of the General Counsel that is signed by the General Counsel. Generally, I believe, it is the practice for committees to make a formal request of the General Counsel for the provision of that document. If you would make that, I would be happy to convey that to the General Counsel.

Senator DASCHLE. Well, we would make that formal request.

[The information referred to follows:]

Please note that the General Counsel declined (in a letter to Senator Daschle dated July 24, 1990) to supply the memorandum referred to on page 28 of the transcript. I enclose a copy of the General Counsel's letter.

TONY IMHOF.

[The General Counsel's letter follows:]

July 24, 1990.

The Honorable THOMAS A. DASCHLE,
Chairman, Subcommittee on Agricultural Research and General Legislation, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: This letter responds to your request, made at a July 12, 1990, subcommittee hearing, for the May 18, 1990, legal opinion of the General Counsel of the U.S. Department of Agriculture regarding the legality of a regulatory proposal to implement a U.S.-Canada open border experiment for meat and poultry products.

Assistant Secretary Jo Ann Smith testified accurately at the July 12 hearing that the General Counsel has concluded that the regulatory proposal is legally sufficient.

I am pleased to confirm for you by this letter that it is indeed our opinion that the proposed open border experiment is within the Department's legal authority.

However, given the likelihood of litigation on the issues treated in the opinion, I believe that it would not be desirable to make public or provide outside the Department an analysis of the legal risks involved in this proposal. We must be sensitive to avoiding any waivers of attorney-client or work product privileges that we may wish to invoke should litigation ensue. Furthermore, release of such opinions would inevitably constrain the full and frank examination of legal and policy implications and risks involved in proposals under consideration within the Department. Therefore, I would respectfully prefer not to release a copy of the May 18 legal opinion. I hope you will be able to understand our position on this.

Sincerely,

ALAN CHARLES RAUL,
General Counsel.

Senator DASCHLE. We are going to, as I said, in a minute just get into equivalency. But as I understand the memo, it clearly expresses grave concern about the legal basis upon which these policies have now been implemented. Is that a fair appreciation of the memo?

Mrs. SMITH. I would not personally agree with the words you have used, no.

Senator DASCHLE. What words would you use?

Mrs. SMITH. Well, I would say it is a legal opinion, an adequate legal opinion, that I think was very carefully thought out that was asked for by us for determination here.

Senator DASCHLE. Based upon that legal interpretation, as you put it, are you more confident or less confident of the legal basis upon which you made that decision?

Mrs. SMITH. I am totally comfortable.

Senator DASCHLE. Based upon that memo?

Mrs. SMITH. Based upon that memo, yes.

Senator DASCHLE. OK. I would be interested in knowing what the legal precedent is for making this decision. Is there any place else in law, to your knowledge, where we—let me constrain it a little bit. Is there any place else in agricultural law where we designate a responsibility for enforcing U.S. law to a foreign official?

Mrs. SMITH. Well, you know, I am not an attorney.

Senator DASCHLE. Well, let me ask the Assistant General Counsel.

Mr. GOLDEN. The provisions that are relied on here, I don't think have ever been construed before this.

Senator DASCHLE. So you would admit it is unprecedented?

Mr. GOLDEN. Well, I wouldn't make so—it is unprecedented with regard to the interpretation of these provisions. I don't have the expertise to say that under no law of the United States has any authority ever been delegated to a foreign country's officials.

Senator DASCHLE. Let me ask you this, then. I would agree that it is unprecedented. I would also wonder where it is in the United States-Canada Free-Trade Agreement that it says these provisions supersede all other provisions of law.

Mr. GOLDEN. It does not say that.

Senator DASCHLE. But you cited the United States-Canada Free-Trade Agreement provision as the basis upon which you have negated other laws which stipulate the department's responsibilities in carrying out inspection to the degree that they are required in law today.

Mr. GOLDEN. Could I answer that question, Senator?

Senator DASCHLE. Yes.

Mr. GOLDEN. I think that all the advice that we have given the agency has been that the statutory basis for their action must be found in the Federal Meat Inspection Act and the Poultry Products Inspection Act. I think it is fair to say that we construe the actions that they are taking here as consistent with provisions in the United States-Canada Free-Trade Agreement and the implementing legislation.

But I don't think that that legislation or that agreement supersedes the provisions of the Meat Inspection Act or the Poultry Products Inspection Act, and I don't think that we could rely on any provision in them that would be inconsistent with the Meat Inspection Act or Poultry Products Inspection Act.

Senator DASCHLE. Well, that is a good answer because that is exactly, I think, the correct interpretation of the legislative history. That point was made over and over again. We are not relegating any responsibility here; the laws of the United States will be supreme.

Now, we are saying, well, but we are going to use the United States-Canada Free-Trade Agreement as our basis, at least in part, according to your opening statement, Mrs. Smith, to delegate the responsibilities for inspection to foreign officials. I agree with the General Counsel; this is a very interesting precedent here.

Let me go back to the memo again for just a minute. As I understand it, hypothetically—not even hypothetically—one could anticipate a lawsuit as a result of this clarification or lack thereof. Does the memo make any indication as to whether they thought you might win or lose a lawsuit on the basis of your legal standing?

Mrs. SMITH. I would have to go back, and I will submit it to you. I don't really remember.

Senator DASCHLE. OK. Let me ask the General Counsel.

Mr. GOLDEN. I think that it discusses risks, but I don't think it, as I recall, makes any final conclusion as to the odds, so to speak, of prevailing in litigation, if there is litigation.

Senator DASCHLE. What do you think? Do you think you can win a lawsuit on the basis of the positions outlined by the——

Mr. GOLDEN. I think it is possible.

Senator DASCHLE. You think it is possible?

Mr. GOLDEN. Yes, sir.

Senator DASCHLE. There is a difference between possibility and probability.

Mr. GOLDEN. I really would rather not talk about the odds.

Senator DASCHLE. I wouldn't either. [Laughter.]

Mr. GOLDEN. I think that we have an interpretation which can withstand legal scrutiny. As to whether a particular court would react to it one way or the other, I don't think I would be prepared to say.

Senator DASCHLE. Well, I am very anxious to see the memo and I appreciate your cooperation in that regard.

As I said, there are a lot of categories of questions and I have exceeded my time. Let me ask Senator Baucus if he has questions, and then we will go to Senator Burns.

Senator BAUCUS. Thank you, Mr. Chairman. Here is the problem I have as a legal matter. The United States-Canada Free-Trade Agreement by itself is not self-executing, as you well know; that is, when the President and the Prime Minister signed an agreement, that agreement had to be ratified by the Congress. More importantly, the implementing legislation, the underlying implementing legislation, had to be enacted by the Congress, and that is what the Congress did. There are many provisions in that United States-Canada Free-Trade Agreement that affect American lives as a consequence of the legislation that Congress enacted; that is, the ratifying legislation.

Now, this open border inspection policy is a policy, as I understand it, that the Department entered into subsequent to the passage of the United States-Canada Free-Trade Agreement, and subsequent to the passage of any implementing legislation. So it is in question; that is, there is a question as to the degree to which the Department can delegate inspection procedures to, say, a foreign entity—let us say the Government of Canada.

Now, that raises two problems. Number one, a nonself-executing agreement between the United States and Canada has not been ratified by the Congress in and of itself. The next question is whether, despite that, notwithstanding the failure of Congress to, in any implementing legislation, ratify, may the U.S. Government, at the behest of the Department of Agriculture, nevertheless go ahead and enter into a nonself-executing agreement that is binding and has full force and authority upon American citizens. I don't think the U.S. Government can.

I don't see how the U.S. Government can delegate authority that is not ratified by Congress to another sovereign country. I don't think we can do that, and that, to me, is the main problem with this agreement.

Now, it could well be that the U.S. Congress, upon consideration of this question, would agree to delegate the meat inspection to, say, another sovereign country. It may or may not, depending upon the wishes of the U.S. Congress.

But absent a legislative determination signed by the President, I do not think that a nonself-executing agreement delegating these kinds of functions and powers to a sovereign country have any legal effect. That is the problem I have.

So if we go back through all of this again, I would just strongly urge the Department to send up legislation asking the Congress to ratify or to enact this procedure. Then I think, Madam Secretary, you will, with 100 percent certainty, be able to say this is OK. But I don't think you can say that today, absent that congressional action, and I don't think the General Counsel's memorandum is going to state that either.

So just to clarify all this, it is clear that this is ambiguous; there is no doubt about it. I don't think anybody can dispute that it is ambiguous, at best. In my view, the action is illegal; it has insufficient legal force and effect. But at the very best, it is ambiguous.

So I strongly urge the administration to solve this thing as quickly as possible by sending up legislation to avoid a lot of the uncertainty that is going to be surrounding this for a long, long time until it is sufficiently firmed up.

Thank you.

Senator **Daschle**. Senator Burns.

Senator **Burns**. I am sure glad I am not a lawyer. [Laughter.]

Sometimes that is an advantage and sometimes it is a disadvantage. I was sitting down pondering a problem the other day and I got to thinking like one, and I jumped up and took a cold shower. [Laughter.]

Senator **Baucus**. Like an auctioneer.

Senator **Burns**. Just as bad.

Despite the legal terms here that have been cited, I think what we have to do is sort of ferret out the primary problem here. Do you think, and are you satisfied, that the inspection practices and procedures of Canada in their plants—do they satisfy your criteria on the product that they are shipping into this country? I would like for you to respond to that.

Mrs. **Smith**. Senator Burns, the systems are almost identical. There seems to be several questions about that. I would like both Dr. Crawford and Mark Manis, who is the Director, Division of Import Inspection of the International Programs Division, to go through it and provide an analysis of comparison for you, as to what we looked for.

Dr. **Crawford**. As you know, Senator, we are in the comment period and are now taking comments on whether or not the general public and experts in the field agree with our contention.

The Canadian system is probably the closest of any trading partner that we have to our system of meat and poultry inspection. It was enacted, as you may know, a year after our own act was passed in 1906, and we have generally recognized the equivalency of the Canadian system ever since that time. Our relationship with them has been the longest, and I think probably the closest of all nations that we have dealt with over the ensuing number of years.

In dealing with our Canadian counterparts, we find equivalency in terms of coverage of plants. We also find that they do have the policy of insisting that domestic product be equivalent to exported product, which we have had and maintained in this country ever since the inception of the program. We have always insisted on that, as has Canada.

In the various fine-tuning of the systems that we have had between Canada and the United States over the years, let me point out that we have had some differences of opinion, but we have been able to reconcile those with Canada. Sometimes they haven't been very easy, but they have been rapid.

You may remember in the early 1980's we had a disagreement over the suitability of an animal drug for use in animals intended for food. The drug had the name of chloramphenicol. It was not approved for use in food animals in the United States; it was approved in Canada. We got into a dispute. We basically presented our case scientifically and toxicologically; Canada presented theirs. They agreed with our position and they took the appropriate steps within a short amount of time.

More recently, we have been engaged with Canada in terms of implementing our new program to protect public health through Listeria monocytogenes monitoring. Canada once again has met us at the table and we have discussed systems that should be put in place that would adequately protect the public health, would be practical, and could be done in both our laboratories. We are making progress in that direction.

With other countries these kinds of disputes take a long, long time and they become extremely difficult. That is because of three reasons, I think—the lack of propinquity to our border; language disagreements that sometimes occur, and so forth, and the lack of willingness to cooperate that we see in Canada.

Someone mentioned earlier the hormone ban and the problems that we had with the European Economic Community over that. With Canada, we have seen a much greater willingness, and we have tried to display the same thing, to achieve true equivalency.

Senator **Burns**. Let us move just a little bit. Our turn-down rate—in other words, meat that didn't meet our standards and was turned down at the border or turned away at the border—what is your rate right now under the present system from Canada?

Dr. **Crawford**. As Assistant Secretary Smith mentioned, Mr. Mark Manis is in charge of that program. I am going to ask him to give you some figures and then I would like to recap what he says.

Mr. **Manis**. Senator, with respect to the rejection rate issue, we commenced doing things differently with Canada in 1989. I know that the GAO reported a rejection rate, and I believe it was 5 percent for 1989; that is in the record.

In terms of what the rate is this year, we have not yet calibrated it. That is normally something we do when we report to Congress at the end of the year. But, in fact, import inspection changes occurred, significant changes, which I believe would sufficiently distinguish rejection rates in 1988 from rates in 1989.

So I think that based upon those differences, one cannot simply look at how many were inspected and how many were rejected in 1988 versus 1989. Certainly, the percentages are different, but I think there are other issues involved as well.

Senator **Burns**. It sounds like a good bureaucratic answer there.

Now, do we handle our inspections from Australia and New Zealand differently than we handle them from Canada?

Mr. **Manis**. With respect to the actual inspection, meaning at the point where the product is before the inspector, the procedures, the requirements, and the accept/reject criteria are all the same. They have not changed either in 1989 or at present. So the answer is they are exactly the same procedures.

Senator **Burns**. I would ask Dr. Crawford, then, are you satisfied with the inspection techniques in Australia and New Zealand?

Dr. **Crawford**. Yes. They remain on the list of countries eligible to export to the United States. Again, with any country, we sometimes have difficulties and we have to meet at the bargaining table to work out new procedures.

Under our policies, any time we implement a new procedure like this Listeria program that I mentioned, it is the obligation of countries privileged to export to the United States to put those same procedures into effect. Sometimes we have difficulties getting our point across, but we are satisfied with any country that is still on the list. That doesn't mean that there isn't tension from time to time.

Senator BURNS. I would just suggest—and I want to thank the chairman for his indulgence here—that we get the idea, and some of it may be hype or whatever, but we get the perception—and, darn it, we live in a town where sometimes perception is fact, you know—that we are playing a little bit loose here—and I am not going to try to refer to the law; I can't talk about it on that basis—but a little bit loose with the concerns that I have with food safety.

I can remember the roux in the stew. You remember we went through that with Australia. That had a definite impact on producers. Producers pay the bill any time there is a loss of confidence in a product because the American public has a hard time identifying from where that meat originated, whether it is American or whether it is Canadian, or whether it is Australian or New Zealand, or whatever.

As we pursue the legal aspect, as the chairman here has indicated that it is his desire to do, I am going to monitor that very closely. But I would just say again that we don't want to get into a position where there is a complete loss of confidence in product because I know producers pay the bill.

Thank you, Mr. Chairman.

Senator DASCHLE. Thank you, Senator Burns. The roux in the stew. That is a legal term, isn't it?

Senator BURNS. No. You don't remember that?

Senator DASCHLE. Oh, I remember the roux in the stew. I just didn't know the terminology.

Senator BURNS. You were very young then, though. [Laughter.]

Senator DASCHLE. I want to talk about equivalency as well, but I just need to go back one more time to legal basis on a couple of points. I think I understood the answer that you made with regard to OGC, and you said OGC had seen it and advised you as to its legal standing prior to the time it was signed.

Mrs. SMITH. No, I did not. I am assuming that we are talking about the one page agreement, not the rule, not the proposed rule. I am assuming you are talking about the one-pager that was denoted as minutes from their agreement. Is that not correct?

Senator DASCHLE. Well, I am talking about the agreement that was signed by Dr. Crawford and by Deputy Minister Morrissey.

Mrs. SMITH. OK, that one-pager.

Senator DASCHLE. That agreement was submitted to OGC and OGC signed off on it prior to the time it was agreed to, right?

Mrs. SMITH. No, I did not tell you that.

Senator DASCHLE. Oh, that is what I understood you to say.

Mrs. SMITH. No, I did not tell you that.

Senator DASCHLE. Well, what actually was the circumstance, then?

Mrs. SMITH. The circumstance that was——

Senator DASCHLE. You certainly didn't submit it to OGC after you signed it.

Mrs. SMITH. The circumstance—and I will let Dr. Crawford also reply, inasmuch as he was the party there——

Senator DASCHLE. OK.

Mrs. SMITH. My instructions to our people that day were to try to come to some sort of an agreement, if they could, on ways that could be looked into to work through a joint kind of system.

Senator DASCHLE. OK. Dr. Crawford, maybe you can elaborate on this.

Dr. CRAWFORD. Yes. We regularly have meetings with our counterparts from Canada, and we had been discussing for some time the possibility of this kind of potential agreement, recognizing that it would be subject to approval by higher authorities, and also in the case of the United States it would have to be the subject of a Federal Register proposal.

The minutes of the meeting that I think you are talking about were signed by Dr. Morrissey from Canada and by me. Below our signatures was a qualifying statement that said any implementation of this agreement will be subject to scrutiny by the U.S. Office of General Counsel. Following the presentation of those minutes to OGC, then eventually the Federal Register proposal was published.

Senator DASCHLE. Could you submit those minutes for the record as well?

Dr. CRAWFORD. Certainly.

Senator DASCHLE. That will be very helpful.

[The agreement referred to was subsequently supplied for the record and follows:]

JOINT U.S.-CANADA OPEN BORDER MEAT AND POULTRY INSPECTION AGREEMENT

FEBRUARY 20, 1990

PREAMBLE

After one year's operation under the Free Trade Agreement, inspection officials in Agriculture Canada and the U.S. Department of Agriculture have jointly reviewed the first year effort and, consistent with the spirit of the Free Trade Agreement, made the following determinations:

I. To jointly participate in an experiment of the open border concept for movement of inspected meat and poultry products between the two countries. The experimental period is not expected to take more than 1 year and will include an evaluation. If successful, the experiment is expected to form the basis of permanent changes in relationships between the two inspection systems.

II. Implementation of the new concept will necessarily occur in stages. When fully implemented, the open border system will be characterized by:

—Full reciprocal acceptance of each country's inspection procedures;

—Continuation of existing label approval procedures reflecting each country's special additive and formulation requirements;

—Export eligibility confirmed through special export stamps only.

A joint implementation team will be constituted immediately to plan for full implementation. A target date for provision of an implementation plan to principals of both parties will be 3/6/90. First phase of implementation will be targeted for 4/1/90.

III. To evaluate the success of the project before the end of the year. The existing FTA Meat, Poultry and Egg Inspection Working Group will direct the evaluation, focusing on consistency with the principles of the FTA.

LESTER M. CRAWFORD, DVM, PH.D.,
Administrator, Food Safety and Inspection Service.
J.B. MORRISSEY,
Assistant Deputy Minister, Agriculture Canada.

[Final draft subject to clearance by USDA/OGC]

Senator DASCHLE. So as I understand it, you signed the minutes of this agreement and it was after signature that you submitted it to OGC for comment, is that——

Dr. **Crawford**. Yes. We didn't sign it, having been the wiser for this down through the years, without putting a box in there saying that this has to be reviewed.

Senator **Daschle**. Is that normal procedure? I would think that normally you would submit it to OGC first and ask, do you have any problems with this, and then go ahead and sign it. Why would you do the reverse in this case?

Dr. **Crawford**. Well, this has been traditional. When we have these meetings, which we call "better relations meetings," generally you keep minutes of them—the highlights thereof. If it requires some sort of change in U.S. policy or something, you generally qualify it. It is kind of like buying a house; you put contingencies on. Our contingency was that this had to be reviewed by OGC.

Senator **Daschle**. And that is normal operating procedure?

Dr. **Crawford**. Well, I have never been involved in minutes quite that weighty, but always in the past you are not bound by the minutes until there is approval by the Department.

Senator **Daschle**. So you have never done that before. Is that what you just said?

Dr. **Crawford**. I have never signed an agreement like this—I have never had this kind of issue come up in this sort of meeting before. We meet regularly with all our counterparts around the globe. We have discussed various kinds of changes in policy, but the minutes themselves do not, in effect, change U.S. policy. That has to be done——

Senator **Daschle**. Yes, but that is exactly what is happening. We are changing U.S. policy with regard to the way meat is inspected.

Dr. **Crawford**. No, not unless we approve the proposal.

Senator **Daschle**. Well, unless we are going under the assumption right now——

Dr. **Crawford**. Nothing has happened to this point; nothing has happened to this point.

Senator **Daschle**. That is right, that is right. Well, I must tell you we can go on about this, and I don't want to elaborate anymore. But it is just highly unusual, and if it isn't it should be highly unusual, and I must tell you I have never heard of it before, where we sign an agreement with another country and put a box down at the bottom saying, well, of course, this is subject to approval by OGC, and then OGC comes back, according to this memo of May 18, and says you are on highly questionable legal ground to be doing this, go ahead and do it.

I am not even sure they recommended doing it, but their legal interpretation was that this was pretty shaky ground, and they provide this interpretation after the fact, after it is signed.

Dr. **Crawford**. You mean after the minutes were taken?

Senator **Daschle**. That is right.

Dr. **Crawford**. Well, we intended to submit it to them. There wasn't an agreement——

Senator **Daschle**. But you said you had never done that before.

Dr. **Crawford**. That kind of thing hasn't come up in a meeting before, no.

Senator **Daschle**. Has it been done in any other way before?

Dr. **Crawford**. Oh, yes, quite often. For instance, in the chloramphenicol and Listeria discussions, we would tentatively agree to what we would present to our principals, subject to review. Yes, that is done.

Senator DASCHLE. So you would say that is common that we would reach an agreement and then submit it to OGC for legal review?

Dr. CRAWFORD. Or to the Assistant Secretary or the Secretary, or whoever needs to have it submitted. The minutes between these joint organizations, such as the Food Safety and Inspection Service and Agriculture Canada, would never be intended to be a binding agreement without some further scrutiny. They are simply minutes.

Senator DASCHLE. Well, on the basis of the legal interpretation you have now been given, does that change anything from your point of view?

Dr. CRAWFORD. Well, I would rather the Office of General Counsel speak to the legal interpretation. Once we got the legal interpretation, we felt the proper thing to do was to publish the Federal Register proposal and take comments.

Senator DASCHLE. But on the basis of the OGC comment, you haven't decided that anything in that particular memorandum was of questionable legal basis?

Dr. CRAWFORD. Well, they made the analysis of it on a legal basis, so I would rather have them discuss that.

Senator DASCHLE. Maybe I could ask Mr. Golden.

Mr. GOLDEN. Yes, sir.

Senator DASCHLE. Dr. Crawford was just saying that you made the interpretation as to the memorandum. Your interpretation in the memo, the OGC interpretation, just to clarify again, is what?

Mr. GOLDEN. I am sorry. I am not understanding the question.

Senator DASCHLE. Well, they submitted the memorandum to you, to the OGC, for comment.

Mr. GOLDEN. They provided us a copy of the memorandum, that is correct.

Senator DASCHLE. You were then asked—they said this agreement is contingent upon comment made by OGC, is that correct?

Mr. GOLDEN. I think what happened was that a member of Dr. Crawford's staff provided a copy of the memorandum with that annotation to an attorney on my staff.

Senator DASCHLE. After the fact?

Mr. GOLDEN. Yes.

Senator DASCHLE. OK.

Mr. GOLDEN. And it was provided to an attorney on my staff.

Senator DASCHLE. And the attorney on your staff wrote a memorandum as to the legal basis upon which this agreement was——

Mr. GOLDEN. No. I think what happened then was that there were some further discussions at the staff level as to whether this initiative could be implemented without a regulatory change or whether it would require a change in the regulations of the agency.

And at that point, we advised the agency that certainly a change in their regulations would be necessary in order to implement the language in this exchange.

Senator DASCHLE. Was that the May 18 memo?

Mr. GOLDEN. No. That, I think, was an oral——

Senator DASCHLE. That was a different memo?

Mr. GOLDEN. I don't think it was a memo. I think it was an oral communication. I think it occurred at a meeting at which we informed the Assistant Secretary and the Administrator that rulemaking would be necessary. And at that point, they went forward to prepare a rulemaking docket.

Senator DASCHLE. But they were submitting this to you—was that the purpose of submission to OGC, was to provide some advice with regard to rulemaking, or was it submitted to OGC as to the legal basis upon which to make this agreement in the first place?

Dr. CRAWFORD. It was submitted to have them check for legal sufficiency.

Senator DASCHLE. Legal sufficiency. So you are saying that the General Counsel got the memo and was given FSIS regulatory change advice, not legal sufficiency advice, is that correct?

Mr. GOLDEN. When we got the memorandum, we were not specifically asked to review it or to provide a legal opinion as to the memorandum.

Senator DASCHLE. But Dr. Crawford just said that is why they submitted it to you, to provide them with the basis for legal sufficiency.

Mr. GOLDEN. It was my understanding that it was informational, and that no action aside from reading the document was taken by OGC with regard to the memorandum which Dr. Crawford and Mr. Morrissey signed. That was provided to us, provided to my staff, and they were told that the agency intended to go forward to have this experiment.

And at that point, I believe, when we understood what they were going to do, we advised them and the Assistant Secretary orally at a meeting that if they intended to take those kinds of measures that they would have to do so by notice and comment rulemaking. And at that point, when they initiated a docket, as we call it, a proposal, a notice of proposed rulemaking, we then prepared a legal memorandum while that proposal was pending in our office.

Senator DASCHLE. The legal memorandum dated May 18?

Mr. GOLDEN. That is correct.

Senator DASCHLE. And the legal memorandum then addresses what Dr. Crawford said he submitted it to you for in the first place, which was the legal sufficiency?

Mr. GOLDEN. It really addresses the legality of the proposal. Although it does refer to the memorandum that Dr. Crawford signed, it is not a document which, in fact, is designed to determine whether that agreement is legally sufficient.

Senator DASCHLE. No, not that document, but the concept of the proposal.

Mr. GOLDEN. Yes. It is really a legal opinion as to whether the proposal that was going to implement that memorandum had legal risks associated with it or not.

Senator DASCHLE. And the legal sufficiency memorandum that we are referring to here, Assistant Secretary Smith says gives you—based on the two references she made—gives you adequate confidence that you are on firm legal standing in implementing this new agreement? I am asking you, Mr. Golden.

Mr. GOLDEN. I think that the memorandum is more nuanced than that, and that it balances the risks and discusses the legal authorities and the risks. It was really not intended to be a recommendation, and I don't think it is a recommendation.

It is a recommendation that the policy officials who are making the decision carefully consider the benefits of the agreement and weigh them against the legal risks before going forward.

Senator DASCHLE. Let me just tell you where I think—I must be honest with you. I think what happened—and I don't want to put words in your mouth—I think what happened is that the Department was just as excited as can be to get this agreement; they wanted to get it and it didn't matter.

In fact, there is a rumor floating around, and it is probably not true, that we gave the Canadians a list of options, saying what do you want to do, pick one. And the Canadians picked one and said, well, we will just go with that. They signed it and then gave it to OGC, saying, what do you think, after the fact.

You said, well, I really think it is pretty shaky legal ground. And, of course, seeing the memorandum of May 18 will determine that. And on the basis of that legal ground, we have been scurrying since May 18 saying, my goodness, how are we going to solidify our legal standing here to make this thing work. That is what I think the scenario was, and I will be very glad to see some refutation of that in the agreement, as well as in the memo that you will submit dated May 18.[4]

But let me go back just to a practical interpretation now of what you are telling me is the legal basis. The law does say that we have to verify that foreign inspection standards are equal to ours and that the verification is pretty clear.

What you are telling me is that the way we have got it set up in the agreement is that a product is inspected; say, 100 pounds of beef is inspected in Canada. That inspection is not challenged at the border any longer. Somebody said there was random inspection. That is not my understanding, but I am pleased to hear that. We will get into the procedure in a minute.

Mr. GOLDEN. If you are referring to a remark that I made, Senator, perhaps I misstated the——

Senator DASCHLE. So there is no random inspection?

Mr. GOLDEN. There is random inspection, and there is random inspection of two kinds required. One is random inspection for species verification and for residues. The statute doesn't say where that has to occur.

Senator DASCHLE. Species verification. That means if they say it is beef, we have to check to see whether it is beef.

Mr. GOLDEN. That is right, and for residues.

Senator DASCHLE. That is pretty tough. [Laughter.]

Mr. GOLDEN. And for residues. That is the roux in the stew.

Senator DASCHLE. And for residues.

Senator BAUCUS. Is that in Canada?

Mr. GOLDEN. The statute doesn't say where that would occur. The interpretation that we are providing says that it could be in Canada.

Senator DASCHLE. But you are saying that it will be in Canada.

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[4] See p. 15 for the letter from Alan Charles Raul, General Counsel, for the response for the memorandum of May 18.

Senator BAUCUS. That is my question.

Senator DASCHLE. Isn't that what Mrs. Smith said?

Mr. GOLDEN. Well, it is within the Secretary's discretion to have it in Canada——

Senator DASCHLE. Well, I know it is.

Mr. GOLDEN [continuing]. And that the proposal would have it done in Canada.

Senator DASCHLE. So I am following this 100 pounds of beef. It has now been inspected in Canada. We say it is equivalent, and I want to get into equivalency in a minute. It comes across the border. Let us say it does hit our requirement for random inspection. They open up the truck and it says beef; it is beef. All right, so they close the door again and it is distributed.

Now, the law says that verification of that inspection has to be made at some point, and what I thought Mrs. Smith said is that if we had to verify that that inspection is proper, we have designated that responsibility, not only for inspection, but verification of inspection to Canadian officials. Is that correct?

Mrs. SMITH. That is what this proposed rule says.

Senator DASCHLE. I have trouble understanding how we work that. I mean, an example would be Soviet missiles. Instead of 100 pounds of beef, let us use 100 missiles. You know, we are supposed to have an inspection of missiles on both sides of the ocean.

I wonder what we would do in the Congress or any place else if we said, well, we are going to have the Soviets inspect their own missiles, and then to verify that those missiles are doing what we say they are supposed to be doing, we are going to have the Soviet inspect the verification of those missiles.

I mean, I would think we would just go bonkers in this country with that kind of stipulation, but that is what we are saying we are doing for meat. Am I missing something here?

Mrs. SMITH. What you are saying is that you don't think the systems are equivalent.

Senator DASCHLE. No, no; I want to get to equivalency.

Mrs. SMITH. And if you go on that premise that they are not equivalent, then there would be a question, and I respect that.

Senator DASCHLE. What I am saying, Mrs. Smith, is even before we get to equivalency, we have no way of knowing whether they are equivalent. We have no way of knowing, and if they are equivalent——

Mrs. SMITH. Well, wait a minute.

Senator DASCHLE. I will even go back further. It is not even equivalency. We are going back to the inspection itself. We have no way of knowing whether, even if they are equivalent, the Canadians are living up to the responsibilities for equivalency. We have no way of checking independent of our word from the Canadians that they are doing it.

Mrs. SMITH. You are saying we should have never allowed any product to come out of Canada and, by the same token, then, we should not be allowed to ship product into Canada today. We started wrong. Using your scenario, then, we have encouraged the wrong system of recognizing other countries to be equal to ours. What you are saying, I think, is that we don't trust your system, so therefore we must have our own inspectors there to do that.

Senator DASCHLE. Let me just restate something President Reagan made famous: trust but verify. [Laughter.]

We have really got to verify here, and we are on blind trust right now. I would expect the Canadians to say, look, we will use your inspection standards—because, frankly, I think they are better than theirs—we will use your inspection standards, but we are going to spot check with our own people to make sure you are living up to the agreement. I mean, that just is common sense.

Senator Baucus.

Senator BAUCUS. Thank you, Mr. Chairman. I appreciate that because I am going to have to leave. I am chairing the oil spill conference that is coming up, a whole different subject here.

Following up on the chairman's point, I think the main point here is that, as I tried to state earlier, Congress hasn't had the opportunity to examine the degree to which, in the judgment of the Congress, meat should be inspected by a foreign country in conjunction, perhaps, with American inspection.

That is the basic question, and that is what this comes down to, as I see it. It is a very major question; that is, the degree to which the people of the United States, the consumers of the United States, want a foreign sovereign to inspect meat that is consumed in America. That is the very basic, fundamental question.

And I might ask in that regard, when was the statute on which you are basing your authority—that is, where the Secretary must verify species and residue—enacted? What year was that enacted? The answer, I think, is 1906.

Senator DASCHLE. It is.

Senator BAUCUS. 1906.

Mrs. SMITH. The original act.

Senator BAUCUS. That is correct, and it has been amended at times since then.

Mrs. SMITH. Yes.

Senator BAUCUS. But the basic thrust that the Secretary must provide verification for species and residue has not been amended since 1906. And I would guess, in the year 1906, that the American people and the U.S. Congress did not contemplate that meat imported into the United States would be inspected by another country as a basic, sole inspection; that is, under a procedure where United States meat inspection officials would not be inspecting the meat.

And it goes to your point, Madam Secretary. I think it may be that when commerce gets more and more open and free and where we are trading more and more around the world that we are going to move toward a system that relies more upon the decisions and inspection capability of people in other countries. I think that is inevitably going to happen to some degree, but I do not think it is going to be the exclusive means or the exclusive device that the American people are going to want.

So I again underline the need for congressional action to determine the degree to which the U.S. Congress, representing the American people, wants a foreign sovereign to be the sole inspector of meat consumed in the United States.

I suspect that there is probably going to be some combination, as the chairman suggests. Maybe the Canadians can inspect, with some spot-checking in the United States. I don't know; I can't predict precisely.

But to repeat, I strongly urge the administration to send up some legislation to clarify this, and I think that will make the American people a little more confident in all this.

I very much understand the concerns of the industry that, my gosh, we get involved in this and somehow the American people might lose confidence in the consumption of American beef, and so on and so forth. I understand that.

I personally believe that the American people are going to have more confidence; they are going to want to eat more beef, more poultry, more imported meat and domestically consumed meat in this country the more they are assured that it is safe and that is healthy.

So I would think it is in the Department's interest, it is in the NCA's interest, it is in all groups' interests to send up legislation here right away, and let us get this thing straightened out to enhance consumer satisfaction and consumer certainty that they are consuming a product that is healthy and safe.

Senator DASCHLE. I am going to get to my equivalency questions, but let me call on Senator Bond for comments or questions that he might have.

Senator BOND. Well, thank you very much, Mr. Chairman. There is a lot about this process that I don't understand and I did want to ask just a few questions so I could broaden my knowledge.

With all due respect, I think that ongoing trade and commerce between the United States and Canada is a little different situation from an arms control inspection. We do have products coming back and forth across the border on a regular basis, and they are, I gather, expected to rely on our inspections while we rely on theirs.

Now, if Canadian products are going to be reprocessed in the United States, are they then subject to U.S. inspection?

Mrs. SMITH. Yes, they would be.

Senator BOND. And what percentage of the Canadian products coming across would be likely to be reprocessed in the United States?

Mrs. SMITH. I would ask Dr. Crawford to respond.

Dr. CRAWFORD. Mr. Manis has recently surveyed that.

Mr. MANIS. Approximately 75 to 80 percent of product exported from Canada is fresh, and therefore further processed.

Senator BOND. So we wind up, then, with inspection on the 75 to 80 percent that is reprocessed?

Mr. MANIS. If it is fresh product intended for further processing, that is correct. For example, a fresh product made into a hot dog would be inspected as it is processed into a hot dog, and would be stamped inspected and passed in a U.S. plant.

Senator BOND. Would that kind of inspection turn up a failure in a Canadian inspection system?

Mr. MANIS. Certainly, during the inspection of processed product, if there is a problem with it, it would not be used and it would be condemned.

Senator BOND. Could you explain to me how you would plan to evaluate this open border experiment? How will this be evaluated?

Mr. Manis. The intent would be to develop a joint committee of U.S. and Canadian officials to review and monitor activity in the United States as well as Canada because this is a bilateral arrangement. And we would intend to conduct surveys of interested parties—in other words, Canadian plants exporting to the United States, as well as U.S. plants exporting to Canada—and determine whether or not the experiment is working.

Senator Bond. Well, would you evaluate not just what the people who are exporting think about it, but somehow whether the importers are getting a fair shake?

Mr. Manis. Sure. It would be both importers and exporters who would be questioned and queried.

Senator Bond. Well, what about the impact on the consumer? Would that be part of the evaluation?

Mr. Manis. We haven't as yet finalized those plans, but to the extent that we can obtain any information—and, certainly, that would be valid information—we would consider it.

Senator Bond. Well, I would hope that you would have some kind of spot check to ensure that the system is working. Wouldn't that be a basic part of an evaluation?

Mr. Manis. In the proposal we would not be looking at the Canadian meat, nor would the Canadians be looking at U.S. meat. So spot checks could, by definition, not be part of the evaluation. Nevertheless, as you indicated a moment ago, since most of the Canadian product is subject to further processing, we do from time to time get reports from our domestic inspectors if there are difficulties with product from Canada or any place else. So, that kind of reporting certainly will be obtained and surveyed during the course of the evaluation.

Senator Bond. Wouldn't it make sense to regularize that evaluation so you would have some check on both the reprocessed and the food products which are subject to no further processing?

Mr. Manis. Yes.

Senator Bond. GAO raised a concern about the lack of a baseline on rejection rates as perhaps making it difficult to compare the new systems. How would you address that concern?

Dr. Crawford. We have reviewed the GAO recommendations, which were primarily in three categories, and we accept them. We believe that we need to keep those sorts of records. We do believe we have adequate basis at the present time for evaluating the two systems because, as you know, under the law Canada has to be equivalent in order to retain the privilege of exporting to the United States. However, we find sympathy with the GAO report and intend to do just that.

Senator Bond. Is there going to be some way that USDA will have continuing or timely information on Canadian plants, or be able to tell if there are problems with a Canadian processing plant? Is there some means of getting information on that?

Mr. Manis. We do have a unique relationship with Agriculture Canada in that we have constant communication, and meet regularly as well. The Canadians review their plants and we are kept apprised of whether a plant is permitted and is eligible to export. So the communication and dialog is ongoing and is very good with Canada, and we will be kept apprised.

Senator **Bond**. Have there been instances where you have gotten the word saying there is a major problem in a foreign country? Have you taken action? What kinds of things can you do?

Mr. **Manis**. It is envisioned during the 1-year experiment that we will require, as will the Canadians, that any loads exported will have to be certified. For example, Canadian product going to the United States will have to be certified by Agriculture Canada. So after the product is prepared and passes domestic Canadian inspection, it is then further certified.

That information will be communicated on each lot with the United States. Therefore, if a plant is not approved or if a load is not certified, then that load would not be permitted to be exported to the United States.

Senator **Bond**. One final question. I understand that the GATT talks are considering sanitary and phytosanitary conditions. With our objectives in GATT, how would that impact this system? How does it relate to this system?

Dr. **Crawford**. You are referring to that set of negotiations which are called sanitary and phytosanitary, and formerly were called harmonization.

Senator **Bond**. Well, I thought I was doing well just to say phytosanitary. [Laughter.]

Dr. **Crawford**. We generally say S and P, Senator.

Senator **Bond**. OK.

Dr. **Crawford**. The idea there is that you need some international standard in order to prevent these nontariff trade barriers based on public health concerns. There are three U.N. organizations that deal with standardization of such things as animal disease, food safety and plant disease.

Built into our agreement with Canada is that if we have a dispute on the use of animal drug the use of any other sort of substance in food, we will go to an international standard and use that as the basis for our discussions, and also that these international standards will be set scientifically. They will not be set based on economic considerations or those sorts of things, but we will look at what is actually a threat to the health and well-being of humans.

That is already working well with Canada as a result of the free-trade agreement. We and the Food and Drug Administration have quarterly meetings in order to iron these kinds of things out. The little pilot between us and Canada that started 2 years ago may very well be the way we deal with problems like the hormone ban in the future.

Senator **Bond**. Thank you, Mr. Chairman.

Senator **Daschle**. Thank you, Senator Bond.

If I could go back to a question I asked earlier because, again, I may have misunderstood the answer, if this agreement goes into effect, will or will there not be spot checks?

Mr. **Manis**. Senator, the question is with respect to the 1-year experiment?

Senator **Daschle**. That is correct.

Mr. **Manis**. During the course of the experiment, both U.S. and Canadian product would be inspected in their respective domestic establishments. If there is intent to export to either country, there would be a checking of the product and certification of the product to ensure it meets all standards of the United States if it is Canadian product.

And at that point, assuming that the product is certified and it is from a plant that is approved in both directions, the product could enter either the United States or Canada.

Senator **Daschle**. So the answer is no?

Mr. **Manis**. With respect to spot-checking?

Senator **Daschle**. Yes.

Mr. **Manis**. That is correct.

Senator **Daschle**. Well, I must tell you it is the best example of blind trust I have ever seen, but let me go to the equivalency issue. We have said several times, and there may be ample cause for saying this, that the Canadian system is virtually identical to the U.S. system. What procedure have we used to make that determination?

Dr. **Crawford**. What we do is each year we must certify that countries that are interested in exporting meat and poultry to the United States are eligible, and so we evaluate each country's system. We do that by sending a team of experts to our counterparts in the various countries.

They sit down and review records; in some cases, review actual plant operations, and determine whether or not the country is both capable, willing and has the legislative authority to operate a program that is equivalent to ours.

Senator **Daschle**. But that doesn't answer my question. What documentation do we have? What do you actually have that you can submit for the record this afternoon which shows conclusively that there is equivalency between U.S. and Canadian inspection?

Dr. **Crawford**. You are just interested in Canadian?

Senator **Daschle**. Just Canadian, that is correct.

Mr. **Manis**. We know that the issue of documentation has come up, and it did come up in the GAO report recently issued. We, to the best that we can, document such decisions, but nevertheless with respect to the reality of getting inspection done and proceeding, we depend perhaps a little bit less on the audit end of our activity and more on an inspection line function.

This is an ongoing issue for us and we are proceeding to improve our ability to conduct and document our reviews, but, in all fairness, do recognize that we don't perhaps have as good an audit trail as perhaps the auditors would like us to have.

Senator **Daschle**. Well, let me just tell you what I just heard. First, I heard you tell me that we, on the basis of legal interpretation, are now going to be making inspection decisions completely on the basis of an inspection system in another country; that all product coming into this country will not be relegated to any verification within the United States. There will be no spot checks.

Now, you have made your arguments that you have the legal authority to do that. You have also made your best arguments as to why that makes sense, but I would assume it would be on one premise; that is, that we have ample documentation as to the equivalency of our inspection systems. Now, what I heard you just tell me is that you don't have any documentation that will give you that assurance.

Mr. **Manis**. I think there are various ways of obtaining assurance, and in that regard we are intending to develop a joint U.S.-Canadian group to look into that issue during the course of the upcoming year experiment.

Senator **Daschle**. But how can we submit our consumers to products coming into this country prior to the time—you say you are going to do that—prior to the time we have made any verification of equivalency? How in the world can we do that?

Mr. **Manis**. We have made a verification of equivalency.

Senator **Daschle**. But there isn't any documentation for it.

Mr. **Manis**. I think that is the issue. The issue that the GAO has presented to us is that while they acknowledge our equivalency determination, they don't see the audit trail to verify that. We do many things that aren't necessarily verifiable by strict audit trails, and I think we have to acknowledge that. Nevertheless, we are working to improve our ability to document. It is the function of time and ability to do that as we carry out the inspection function.

Senator **Daschle**. But I am still unclear. What procedure are you referring to that you have relied upon so far? What is it that you do on a regular basis to ensure equivalency?

Mr. **Manis**. With respect to Canada?

Senator **Daschle**. That is right.

Mr. **Manis**. We check and keep abreast of their laws. We meet regularly with Agriculture Canada and discuss issues of concern. We are familiar with their procedures. We have visited their plants and we have an ongoing relationship over numerous years.

In fact, we have the unique opportunity of meeting regularly with Canada either here or in Ottawa that we do not do with other countries. So there is a close interchange and review that is unique. And, really, we cannot point to any other relationship with any other country where we have functioned in that capacity.

Senator **Daschle**. I have got to tell you, it really is incredible to me. You are asking consumers to put their entire confidence in the Department of Agriculture, and when the Department of Agriculture is asked what procedure do you use to document equivalency, you say, well, we look at their laws, we talk to them from time to time, once in a while we may drop by one of their processing facilities, and on the basis of that we are going to forgo any U.S. verification of imported product.

Dr. Crawford.

Dr. **Crawford**. We do have documentation. The issue raised by the GAO was how much documentation, and we accept that and we will be working to improve the documentation, and also to make our verification more transparent and have a better audit trail.

For instance, one of the major concerns that has been expressed in the past, at least by GAO and OIG, is what do you do in order to determine that the residue program is equivalent to ours, and we do have information with respect to that which we can provide for the record.

And then the second major concern, and really the only two concerns in terms of the safety of the product, is the bacterial contamination, and we have documentation with respect to that.

The question is how much verification and how much do you need in the file. As I said earlier, we accept that GAO has raised legitimate questions and we will be working to improve that over this 1-year experiment period. I remind you again that nothing has happened to this point.

Senator DASCHLE. No, but it will go into effect prior to the year. I mean, you are going to be enacting this thing.

Dr. CRAWFORD. We have not determined whether or not it will go into effect.

Senator DASCHLE. Well, that is a good thing. [Laughter.]

Dr. CRAWFORD. Well, that is the way it works.

Senator DASCHLE. But you have to admit that you do not have adequate documentation to verify certification that there is inspection equivalency, to admit that prior to the time we implement this new inspection program.

Dr. CRAWFORD. We didn't admit that we didn't have adequate documentation to assure——

Senator DASCHLE. Oh, I thought that is what you just said.

Dr. CRAWFORD. No, no. We don't have as much as GAO would like for us to have, but I am confident that there is equivalency, and we can provide information for the record to establish that. You might say you need more.

Senator DASCHLE. So you are suggesting that GAO is requiring verification beyond what is adequate?

Dr. CRAWFORD. They are requiring more information.

Senator DASCHLE. But you just said you have adequate, but it is not what the GAO has requested.

Dr. CRAWFORD. Well, we will have to evaluate what they said.

Senator DASCHLE. Your implication is that they are requiring you to produce more than what is adequate.

Dr. CRAWFORD. Well, we will make the determination based on the report which, as you know, we only got this week. But we are not arguing with the fact that we could always use a little more justification, a little more documentation. But we are not saying to you that we don't have adequate verification for me as Administrator to make the judgment that they are equivalent, because that is required by law each and every year for all of the countries that export here, not just Canada.

Senator DASCHLE. Well, we mentioned the law a couple of times. Let me ask with regard to law in Canada and in the United States, are there any circumstances in which a Canadian processor may add ingredients under their law to products such as sausage which are not permitted for U.S. processors?

Dr. CRAWFORD. That is the purpose of this group that meets regularly to review basically several things that will be covered under these——

Senator DASCHLE. Well, is it yes or no?

Dr. CRAWFORD. Yes. The question is, we meet regularly. The answer is no.

Senator DASCHLE. No, no. The question I am asking is are there any circumstances in which a Canadian processor may add ingredients under their law to products such as sausage that are not permitted U.S. processors?

Dr. CRAWFORD. We have a list of their food additives. As I mentioned, we have had a dispute which is now settled on some animal drugs. We have none ongoing in terms of food additives that I am aware of. We can provide for the record what they can and what we can add.

Senator **Daschle**. But you don't know the answer to that question?

Dr. **Crawford**. Yes. We have the files which basically are done side-by-side. We don't have any disputes with them on what can be added to their sausage, no.

Senator **Daschle**. So I take it your answer, then, is no, there are no additives in Canada which are legal there which are not legal here.

Dr. **Crawford**. As far as I am aware, based on the side-by-side, unless there has been a recent approval there that was not brought to our attention, which I don't think is the case, we don't have any problems with them in that regard.

Senator **Daschle**. But that isn't what I'm asking, whether you have problems with them. The question I am asking is whether there is any legal additive in Canada that isn't legal here.

Dr. **Crawford**. You mean a substance itself or the level that it is used, or both?

Senator **Daschle**. Well, I am going to get to the level, but I was talking about substance now.

Dr. **Crawford**. With respect to sausage, we have recently evaluated that and I am not aware of any that are different. There may be a level that is different. We can provide that for the record.

Senator **Daschle**. Well, let us get into nitrite. Is the nitrite level different in Canada than in the United States?

Dr. **Crawford**. We had a meeting where that was raised. I can provide those minutes for you.

Senator **Daschle**. Well, you don't know?

Dr. **Crawford**. I will once I check the files.

Senator **Daschle**. I mean, the answer is, I think, yes. The nitrite level in Canada is higher than in the United States, and the reason I raise the question is obvious. I mean, you know, we are talking equivalency here. Now, we have had vicious debates in this country about what level of certain additives is acceptable by our standards. We have had vicious debates about whether or not we even ought to provide additives on an acceptable list.

Now, I honestly don't know the answer with regard to whether our list is identical to theirs. Frankly, I don't think it is, but I will appreciate your submission for the record there.

[The information referred to is retained in the subcommittee file. See letter on pp. 14–15, dated August 6, 1990, from Jo Ann R. Smith, Assistant Secretary, Marketing and Inspection Services, Department of Agriculture, Office of the Secretary.]

Senator **Daschle**. But I do know that the level of acceptable additives is much higher in Canada than in the United States. So here you have a perfect example of what we are talking about. You say there is adequate documentation. The GAO says there isn't adequate documentation about equivalency.

We are taking one specific example; that is, the nitrite levels acceptable in Canada versus the United States. We know that Canada allows a higher nitrite level, but that product is going to come into this country and it is not going to be inspected, and you have an equivalency dilemma here. Who is right; is it Canada or the United States?

If nitrite is an advantage for the Canadians and it puts us at a very distinct competitive disadvantage, not to mention whatever safety hazards that may be involved, how do we address that?

Dr. **CRAWFORD**. Let me tell you how we address that.

Senator **DASCHLE**. OK.

Dr. **CRAWFORD**. There are national standards for these kinds of things. There are also international standards, and what we attempt to do when there is a variance between two nations and it is threatening to interfere with trade is we sit down in these quarterly sessions and try to negotiate based on the international standard.

I can't tell you off the top of my head whether or not the Canadian standard is also the international standard. If it is not, then we will have to reach an agreement. They will either have to change or make some sort of adjustment.

Senator **DASCHLE**. Let me ask one additional question pertaining to an incident that occurred just last month. The inspector in Sweetgrass, Montana, reported higher percentages of contaminated meat coming in from Canada through his facilities.

On May 11, the inspector received 13 assignments to run product exams. He refused entry to 5 of the 13 based on findings of fecal material, ingesta, hair, bruises and blood clots on the samples. Of the 175,799 pounds of meat inspected, the inspector refused for entry 64,638 pounds. This is a 36 percentage rate of failure for 1 day.

On May 18 and 19, the inspector refused entry to 13.9 percent and 22.5 percent, respectively, of the meat he inspected. These represent random samples selected for inspection. They were pulled presumably by the Canadians. Meat not marked for inspection went through without reinspection.

With refusal rates this high, how is it that we can justify not having spot checks?

Dr. **CRAWFORD**. We evaluated those figures, and Mr. Manis, who conducted the investigation, will share with you the results.

Mr. **MANIS**. Senator, of course, those were not the inspector's rejection rates for the year.

Senator **DASCHLE**. No; they were just 3 days.

Mr. **MANIS**. Right, but over a year, we do know that the rejection rates for Canada, much less for Sweetgrass, are not in that magnitude. So I think the rejection rate should be counted for a whole year, not necessarily rejection rates on a given day at a given location. And to my understanding, that is not the rejection rate for Canada.

Senator **DASCHLE**. No one ever said it was the rejection rate for Canada, but I am just citing 3 days and, using that as an example, asking a fundamental question. How can you not have spot checks, given that kind of product coming into this country?

[No response.]

Senator **DASCHLE**. I guess the answer speaks for itself. Well, there were some questions pertaining to Listeria I wanted to ask, but I will do that for the record.

[The questions of Senator Daschle follow:]

QUESTIONS BY SENATOR DASCHLE

There have been reported incidences of meat products from Canadian plants contaminated with Listeria. Consumption of food contaminated with this bacteria can cause listeriosis, a rare but potentially serious disease. Most vulnerable are people with weakened immune systems: infants, the elderly and the chronically ill. One report suggested a possible link between a contaminated hot dog manufactured by a Canadian plant and the death of a Canadian woman.

1. Please provide what information you have on the Listeria issue with regard to the Canadian inspection system?
2. What actions did USDA take in response to these incidences of Listeria contamination?
3. Was any effort made to require Canada to tighten its procedures to detect Listeria contamination?
4. What procedures does the United States employ to detect Listeria contamination and to prevent food products from being sold that might be so contaminated?
5. What procedures does the Canadian Government employ?
6. Are there any differences in the United States and Canadian procedures with regard to detection of Listeria contamination?
7. Are any steps being taken to remove these differences?

[See pp. 138–318 for the responses from the Department of Agriculture, Office of the Secretary, dated September 4, 1990.]

Senator DASCHLE. I have kept you long enough. There is a vote on the floor. I will say this. I am going to submit the record for the entire hearing as comment from this subcommittee so that USDA has an adequate opportunity to respond to each of the points raised. It may take longer than 30 days to do it, but I must tell you I think it is critical that we do. And, frankly, I am not at all satisfied that we have resolved many of the issues raised today. I must thank you for coming this afternoon, Mrs. Smith.

I am going to recess the hearing long enough to go vote. I would ask that Department representatives stand by because, as I like to do in my hearings, I would like to call them back to the table to address some of the concerns raised by subsequent testimony.

[The prepared statement of Mrs. Smith appears at the conclusion of the hearing.]

Senator DASCHLE. With that, let me recess the subcommittee for now, and I will be back very briefly.

[Recess.]

Senator DASCHLE. The hearing will come back to order. Let me call to the table our next witness, John Harman, the Director of the Food and Agriculture Issues Branch of the General Accounting Office. I know he has additional people with him, and I will ask him for the record to introduce them at this time.

To each of you, let me express my apologies for keeping you waiting as long as I have, but this is obviously a very complex issue and one that isn't easily explained, especially for the record. I appreciate your indulgence. I thank you for being here and would invite you to introduce the other people who have accompanied you and ask you to proceed with your testimony as you see fit. I emphasize that the entire statement will be submitted as part of the record.

STATEMENT OF JOHN W. HARMAN, DIRECTOR, FOOD AND AGRICULTURE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY EDWARD ZADJURA, ASSISTANT DIRECTOR, HEALTH AND FOOD SAFETY ISSUES, AND LOUIS SCHUSTER, STUDY COORDINATOR

Mr. HARMAN. Thank you, Mr. Chairman. We are indeed pleased to be here today, as we always are, to discuss the work that we do, in this case dealing with the Canadian meat issue, as well as our views on the recent events and proposals to eliminate the streamlined procedures through an open border proposal.

Before I begin, I would like to introduce to the chairman, on my right, Ed Zadjura, who is the Assistant Director responsible for our work in the health and food safety area, and on his right is Lou Schuster, who is the individual responsible for the work that forms the basis of my testimony.

AREAS REQUESTED FOR EXAMINATION

I am prepared to summarize and I will be summarizing my statement. I am not sure what I can add, really, to what has already been said in many ways, but I will go through it. There have been a great deal of issues raised, many of which we raised in our report, that have been brought into the record. There were five areas that we looked at for Representatives Byron Dorgan and Tim Johnson.

First, FSIS, as was discussed here at great length, could not document its determination that the Canadian meat inspection system is at least equivalent to the U.S. system.

I know, as auditors, we frequently get hit with this allegation—maybe that is too strong a word—that we are interested in the paper trail for its own sake. But I think here our concern goes beyond that to the extent that if there is a problem that occurs and if someone does ask USDA, how do you know it is equivalent, we feel they ought to be in a position to make a strong case. Otherwise, there could be some serious ramifications in terms of the consumers, and I think that is a concern of ours as much as just the simple idea that you ought to be able to document your decisions.

QUESTION OF ADEQUATE DOCUMENTATION

Senator DASCHLE. Mr. Harman, let me just stop you there because that obviously is one of the points that was raised. They said that their documentation is adequate; that you are asking for additional documentation. They saw no objection to meeting your needs for additional documentation, but adequate documentation was available.

Do you feel that that is the case? Are you satisfied with that?

Mr. HARMAN. No, we were not satisfied, and I will let Ed and Lou, to the extent that they care to do so, expand on that. But at the very least, it is not a systemic approach to what has to be done in terms of determining equivalency for Canada. It is not the same kind of documentation that they are doing for other countries.

But let me just let Ed and Lou talk about some of the questions they asked and what they found as they were trying to determine this equivalency.

Senator **DASCHLE**. OK.

Mr. **ZADJURA**. Yes, Mr. Chairman. The basic problem, I think, comes in that we have a system that requires that any country, not only Canada, exporting meat to the United States have a system that we determine is equivalent to ours. Equivalent doesn't mean exactly identical, but it means relatively close and we have confidence in it.

FIVE KEY AREAS PERTAINING TO RISK ASSESSMENT

USDA over the years has gone about doing that in several ways; they have revised it. Several years ago, because of criticisms about the prior systems and the prior methods they used, they came up with a risk assessment system that looked at five key areas—residues, disease, economic fraud, contamination, and processing.

They are in the process of applying that to every other country. They have chosen to exempt Canada, and basically what we have asked them repeatedly is to provide evidence that Canada's system is equivalent. It may very well be, but it is very difficult to tell.

Essentially, you are being provided with assurances: trust us, we are familiar with them, we know. If a consumer in this country gets sick or dies from imported beef, that is not going to provide a lot of assurance. As Senator Baucus and Senator Burns pointed out, it could be devastating for our own meat industry.

CASES OF LISTERIA

Senator **DASCHLE**. Are there not some cases of Listeria where that actually happened?

Mr. **ZADJURA**. There have been recalls recently of hot dogs—three, I believe—that have been extended to the entire Nation from a Canadian plant.

Senator **DASCHLE**. Three cases?

Mr. **ZADJURA**. Yes—well, recalls.

Mr. **HARMAN**. Three recalls.

Senator **DASCHLE**. Three recalls.

Mr. **ZADJURA**. It originally started out in the Northeast and then it was extended further. USDA pointed out that much imported meat is reprocessed, and that is true, and it would get some inspection then. But hot dogs, for example, already come in complete. They had Listeria in them; they have been recalled. There was apparently a serious case in Canada that may have been linked to these hot dogs.

Clearly, the fact that maybe most of the meat at some point may get another inspection is, to some extent, reassuring. But the fact of the matter is these hot dogs wouldn't have been; they would have gone right to a retail store and been sold to the consumer. And if it wasn't for a port-of-entry inspection, somebody would have eaten these hot dogs and could have become ill, and it would have slipped through the system.

WHAT IS THE EQUIVALENCY WITH REGARD TO SUBSTANCE?

Senator DASCHLE. Let me ask you a question that I guess they are going to submit for the record, but it would be helpful for me to know to whatever extent you can shed light on it. What is the equivalency with regard to substance? Are there substances utilized in Canada that are not legal in this country, either in form or in degree?

Mr. HARMAN. I don't think we know the answer to that.

Mr. ZADJURA. No, we don't have a definitive answer to that.

Senator DASCHLE. OK.

Mr. ZADJURA. There can be some differences because it is required to be equivalent to, if not exactly identical. If there is a clear standard here, you would certainly presume that it wouldn't be allowed.

Senator DASCHLE. But under the new proposal, it would be allowed.

Mr. ZADJURA. Yes; if it was acceptable to the Canadians, yes.

Senator DASCHLE. Right. So, in a sense, you would have a double standard. You would have products processed in Canada with substances either to a degree or in form that are not legal in this country coming into this country without any inspection.

Mr. ZADJURA. Yes. The Department was making the distinction there at one point that Canada requires that everything exported be the same as everything domestically consumed. That is true, but as you are pointing out, that may be still different than our standard.

Senator DASCHLE. That is right.

Mr. HARMAN. And I think that the question there has to be what process—if you go into this new proposed procedure, what process would you have—it is exactly the same question as to the equivalency question—to assure that that doesn't happen. There are other systems, international standards and those sorts of things, that come into play.

Senator DASCHLE. But you are saying that there are tangible documents which indicate equivalency or lack thereof for other countries that do not exist for Canada. Is that a correct statement of the current situation?

Mr. ZADJURA. Yes. USDA revised their system back in about 1987 and came up with these five areas, and Lou can correct me if I am wrong, but they have been systematically going through all countries and working through these five critical areas to perform an evaluation and an assessment under this risk assessment method, and they have done two of them, I believe, for all countries and they have two more that are going to be done this year as a part of doing that overall evaluation, comprehensive evaluation.

They have exempted Canada from that evaluation process, and basically what their equivalency consists of now is essentially some familiarity with plant reviews from when USDA used to do them. USDA has now done away with that. The Canadians are doing the plant reviews in lieu of FSIS personnel.

You know, they do have knowledge of the laws. Whether there is a comparison side-by-side of their law and their standards and their levels with the U.S. ones—that does not really exist, not a current one. USDA has not reviewed all five of these areas and put together an evaluation that shows what they have done, what methodology they have used, what specific things they have looked at, how they have evaluated any differences to see whether it is close enough to be equivalent, something that you can really sit down with and say, here is what we have done and based on that, based on our methodology, our scope, our standards, U.S. laws, this system is close and it is equivalent. That does not now exist.

Senator DASCHLE. I interrupted you, Mr. Harman.

Mr. HARMAN. That is fine. I would encourage you to do that as I go along.

SECOND ISSUE HAD TO DO WITH THE STREAMLINED PROCEDURES THAT ARE CURRENTLY IN EXISTENCE

The second issue we looked at had to do with the streamlined procedures that are currently in existence that were put into effect in January of 1989. Looking at those, all Canadian shipments are no longer unloaded at an inspection facility and given a routine visual inspection for general condition that was done previous to that.

SELECTED SHIPMENTS ARE STILL SUBJECT TO COMPREHENSIVE INSPECTION FOR WHOLESOMENESS

However, selected shipments are still subject to comprehensive inspection for wholesomeness. These new procedures are controversial in and of themselves because Canadian plants are given advance notice for shipments that FSIS has selected for inspection and Canadian inspectors pull the samples. These issues, of course, will cease to be issues if the open border concept is adopted.

Senator DASCHLE. Let me see if I understand what you are saying. Right now, before we even get to the elimination of spot checks, we call them and say, all right, we know you have a couple of truckloads of beef coming in, we are going to inspect these lots.

Mr. HARMAN. We provide to them the samples to pull.

Senator DASCHLE. The samples to pull, so they check them?

Mr. HARMAN. They pull the samples.

Senator DASCHLE. They pull the samples. We then do not look at any other samples in that particular load?

Mr. HARMAN. That is correct. It is a statistical——

Senator DASCHLE. Only the samples that we tell them we are going to look at?

Mr. HARMAN. That is right. They pull the sample. It is placed in a certain position in the truck and then when it crosses the border at an inspection station, it is inspected at that point. Now, the problem that one can get into there is that if a Canadian inspector pulls a bad product, he is faced with a dilemma in the sense that he is also charged with not allowing contaminated meat to get into the system.

So we have been told that on occasion they will throw away or discard that sample and substitute it with another sample, which does influence the sampling and tends to invalidate the results.

Senator DASCHLE. So they find the contaminated meat, or find something wrong with the meat and replace it with meat that will meet the inspection standards?

Mr. HARMAN. That is true. Now, with items like case items, it probably is unlikely that is going to happen because they are going to pull the case and place it into the truck and then it will be inspected.

Mr. SCHUSTER. Senator——

Senator DASCHLE. Well, that makes me wonder—go ahead, Mr. Schuster.

Mr. SCHUSTER. We have not verified any individual instances ourselves where that has happened. We have been told that it is a very likely possibility that Canadian inspectors would do that if they were faced with that situation. And, of course, some of USDA's own inspectors have claimed that it is happening.

Senator DASCHLE. But the fact that we notify is clearly the operating procedure today; that is, we notify them what product is going to be inspected.

Mr. HARMAN. That is correct.

Senator DASCHLE. How, then, can one explain what happened in Sweetgrass, Montana, on May 11 where, after notification, this product comes across the border, this inspector looks at it and finds 5 of the 13 quantities that were to be inspected had fecal material, ingesta, hair, bruises, and blood clots?

Mr. HARMAN. That is very hard to understand.

Mr. ZADJURA. One possibility, Senator, is, of course, that it is frozen, packaged, boxed meat and they have selected a box as the sample. In that case, it would be hard for the Canadian inspector selecting it—he is just physically tagging a box and saying put this in the back of the truck.

Mr. SCHUSTER. Let me clarify that, too. For the 3,000 countrywide sample, the random sample that they take with those inspections, the Canadians pull the sample. The Sweetgrass inspector—I think those violations that he has found have been under their intensified inspection program, and as part of that program the USDA inspector will pull those samples.

Mr. ZADJURA. Essentially, when USDA finds violations from a plant, they make the next 15 loads stop automatically at the border to be inspected. So in that case, that is under the intensified system. But under the random system it could still happen because the Canadian inspector is selecting, in some cases, packaged beef and it would not be noticeable until the U.S. inspector actually opens the box, thaws the meat out and looks at it.

Senator DASCHLE. Well, I am amazed, frankly, that in that particular instance you had a 36-percent failure rate for 1 day, and then on the 2 subsequent days 13- and 22-percent failure rates. Is that an anomaly? That rate seems just abnormally high, and yet they just happen to be 3 particular days that don't have any basis for consideration of any abnormal circumstances.

Mr. HARMAN. Without looking at that in detail, it would be hard to understand. USDA in its testimony said that they did do an investigation of that. I didn't really hear detailed information on what they found explaining those particular 3 days.

It is true that the average rejection rate is much lower than 36 percent or 20-some percent or even 13 percent. But it could very well be a particular plant was having a problem that day, or those 3 days. Maybe there was a problem with a plant. You just don't know unless you go back and look into it.

Senator **DASCHLE**. What is disconcerting is that it made it all the way through the Canadian inspection system, however that happened. Again, going back to your earlier contention, we don't have adequate verification that their inspection criteria is equivalent to ours. So on blind faith, this could happen every day and we will never know.

Mr. **HARMAN**. Well, under the proposal, with no inspections, if there is a breakdown in the Canadian system, or vice versa, if there is a breakdown in our system, either way, that could occur. That means that the verification of equivalency becomes even more important and is really the cornerstone of the proposal.

Senator **DASCHLE**. Well, go ahead.

THIRD AREA DEALS WITH THE REJECTION RATES OF CANADIAN MEAT

Mr. **HARMAN**. The third area, and this ties right into what you are talking about, deals with the rejection rates of Canadian meat, which were higher in 1989 than they were in 1988, but the causes and significance of these higher rates are unclear.

USDA mentioned that there are different methodologies; a different system was used in those 2 years, and that is absolutely correct, which would affect the results. But in 1989, 3 percent of the 3,000 randomly-selected lots failed, and 8 percent of an additional 1,866 lots were rejected under the intensified process that we just talked about. This contrasts with 1988 when 1 percent of almost 13,500 lots failed.

FSIS CANNOT ACCOUNT FOR THESE DIFFERENCES

FSIS cannot account for these differences in the 2 years or determine whether they were important, in part because there is no criteria for what an acceptable rejection rate is. Now, that becomes important to us for the same reason as the idea of making sure that Canada has an equivalent system.

CONSUMER STANDPOINT

From a consumer standpoint, to know that the systems changed doesn't give a whole lot of comfort, I wouldn't think, to know that 3 percent of the meat may come in contaminated. So I think it is important to understand, to the extent that the Department can, why this occurred, and that was one of our recommendations in the report.

FOURTH—U.S. PLANT OFFICIALS SATISFIED WITH THE TREATMENT RECEIVED FROM CANADIAN SYSTEM

Another thing we did is talked to 25 U.S. plant officials who export a substantial amount of meat and poultry to Canada to see whether they were satisfied with the treatment they received from the Canadian system, and they were satisfied.

FSIS' OPEN BORDER PROPOSAL RAISES LEGAL AND POLICY ISSUES THAT NEED TO BE ADDRESSED DURING THIS DECISIONMAKING PROCESS

Finally—and it is an issue that you discussed at some length starting the hearing off—FSIS' open border proposal raises legal and policy issues that need to be addressed during this decisionmaking process. I think it was Senator Burns that quoted from our report what our position on that is.

LEGAL PERSPECTIVE

From a legal perspective, there is a question of whether the open border proposal conflicts with the existing legislation. From a policy perspective, FSIS, in our view, needs to address the questions of how well documented the equivalency of the two systems is and the unexplained increase in the rejection rates from 1988 to 1989. Also, in evaluating the success of the proposed test, we think they need to assess the extent to which the proposal ensures the safety and wholesomeness of imported meat and poultry not just the economic side of it.

Currently, as we understand their plans, their evaluation will not address whether or how this will be done; in other words, how it is going to ensure food safety. Senator Bond was touching on that to an extent in asking how the United States is going to know whether the rates go up or go down or how safe it really is? That is difficult when you eliminate all the inspections.

I would like to point out, though, Mr. Chairman, that we in no way are being critical of the concept of an open border with Canada. In fact, our office has been generally favorable toward efforts to create a more market-oriented economy, particularly in agriculture. I know that is maybe a heresy to say in this room, but we have said that before.

Senator DASCHLE. You say it at your own peril

Mr. HARMAN. We say it at our own peril, that is correct.

WE DO BELIEVE IT IS IMPORTANT THAT POTENTIAL CONSUMER CONCERNS ABOUT FOOD SAFETY BE ANTICIPATED AND ADDRESSED

However, we do believe it is important that potential consumer concerns about food safety be anticipated and addressed to the extent possible before proposals such as the one being made by FSIS are implemented. It is in this context that we recommended that the Secretary review and document the equivalency of the Canadian system, investigate the reasons for the higher rejection rates and, if the open border test is approved, incorporate into the evaluation plan an assessment of the impact on food safety.

That completes my summary, Mr. Chairman. We would be pleased to answer any more questions you might have.

Senator DASCHLE. Well, I must say I am one of those who voted for the United States-Canada Free-Trade Agreement with a great deal of reluctance, indicating at the time that I was willing to give it the benefit of the doubt, that we were going to revisit it from time to time.

But if this is any indication of what it means, if these are the implications of the free-trade agreement, then I must tell you I think this agreement is very short-lived. From a legal, administrative and procedural point of view, if these are the ramifications, that agreement is in big trouble. This country just cannot accept designating responsibility for some of the fundamental aspects in meat inspection and equivalency of that inspection to a foreign country. It goes to the very issue of sovereignty, it seems to me.

But let me just ask you, you heard the legal justification explained to us today, section 708(d) and section 10 of the free-trade agreement. You have obviously examined those two bases with regard to their legal standing. You are not satisfied, obviously; you have said you are not. Why are you not satisfied? Why is it that those two provisions of law don't meet the test for legal standing in coming to terms with this agreement?

Mr. HARMAN. Well, let me say first that we haven't looked at this—our legal counsel and our General Counsel have not looked at this in the detail necessary to offer any kind of formal opinion on whether their position is correct or not. But given what I heard today, given what I heard about the memo and what we have discussed with people on the USDA legal memo, there is certainly a major, major question about whether this process that they are proposing is in conformance with the existing legislation.

I do not see that the free-trade agreement is particularly relevant here in terms of whether or not they can do that.

Senator DASCHLE. But they cite that as one of the two justifications.

Mr. HARMAN. I know they cite that, but they cite sections of that agreement which are principles which the two countries will follow. There is also a provision in the agreement providing that it will not override existing legislation, and so then it gets down to what authority does the Secretary have to delegate inspection of products that are imported into this country.

To us, based on what we have seen so far, there is a major question about whether they have that authority. The USDA memo which talks about a substantial risk—I am not sure those are the words they used, but at least a risk of litigation, would seem to me to indicate that they are not altogether sure either that they are on solid legal ground. What I heard here today does not give me comfort that they are on solid legal ground.

Senator DASCHLE. Let me ask you something that you may or may not be prepared to answer. Do you know of any precedent where this is being done, where we have designated a fundamental responsibility performed by personnel within our own government to another government?

Mr. HARMAN. I am not personally aware of that. Do either of you gentlemen know?

Mr. ZADJURA. No, other than where it is provided by law specifically.

Senator DASCHLE. But do you know where there are provisions of law that would allow that?

Mr. ZADJURA. Well, I believe the second section in the Meat Inspection Act where it said that they would do random inspections by the exporting country.

Senator DASCHLE. But that is the law.

Mr. ZADJURA. That is right.

Senator **Daschle**. I am asking is there any precedent, to your knowledge, other than that particular provision of law.

Mr. **Zadjura**. No. My understanding, Senator, from talking to our attorneys is that there is even a question of law relating to the ability of Federal officials, for example, to delegate authority to non-Federal officials, State officials, Governors, and the like. And, certainly, I would think that that question would extend to the authorities of a foreign country.

Senator **Daschle**. Well, that is certainly my understanding. I also wonder as to the precedent that we have set. You have one precedent in delegated responsibility; you have another precedent directly related to that delegated responsibility of requiring an inspection based upon some appreciation of equivalency, but then also requiring verification of that inspection by the same people who have the initial responsibility for inspection.

I honestly don't know where that has ever been done. You can think of a number of analogies here. But, to your knowledge, in all the work you did in investigating this matter, did you ever find any precedent for that?

Mr. **Zadjura**. Well, as a matter of fact, Senator, it was FSIS' position stated to the Canadian Government that that was required by U.S. law, by the Federal Meat Inspection Act.

Senator **Daschle**. That what was required?

Mr. **Zadjura**. That we reinspect under——

Senator **Daschle**. That we reinspect?

Mr. **Zadjura**. That we reinspect under the Federal Meat Inspection Act all product entering this country.

Senator **Daschle**. When was that position made known to the Canadians?

Mr. **Zadjura**. Well, I think as recently as back in January and probably even early February, there had been some, let us say, complaints in the late fall and into the winter of 1989 from the Canadians that we were inspecting too much imported meat and we shouldn't be doing this, and we were harassing their processors by doing that, and calling for doing away with the inspections and the fees.

FSIS, as you know, internally prepared papers on what their position was on this question, and was effectively defending the position that they were required to do this by law. Subsequently, after this agreement was signed, there has obviously been some reconsideration.

Senator **Daschle**. One would have to conclude that the Canadians put an inordinate amount of pressure on the Department of Agriculture to back off. That is what I have to conclude. And I don't want to put words in your mouth, but if you have FSIS telling the Canadians, look, the law requires us to verify what you are doing, and they do that in January and then in May we come up with an agreement that says, all right—you know, if I were the Canadians, I would say what happened to the law.

But, obviously, since it was in their interests for us to concede this major point, it really does make me wonder about the internal legal rationale created within the Department of Agriculture to come to this position. Frankly, I am bewildered, to say the least.

Mr. **Harman**. Let me make one other point, too, about the agreement—the free-trade agreement, that is. In fact, it provides for spot checks as long as the activity is no more frequent for the importing country than is required for domestic processors. So there is provision in the agreement for spot checks.

Senator **Daschle**. They have to be reciprocal spot checks.

Mr. **Harman**. They have to be reciprocal, that is right, but they are provided for.

Mr. **Zadjura**. Which, by the way, Senator, the Canadians questioned. That was one of the questions they raised, and FSIS' response was to defend the number of inspections they were doing by citing all the reinspections they do of U.S. meat, and saying, obviously we are not reinspecting it more than we are inspecting our own; therefore, it is in compliance with the free-trade agreement.

Senator **Daschle**. Well, I was going to ask that. Are the Canadians spot-checking U.S. product today?

Mr. **Zadjura**. The Canadians do a destination inspection at the processing plant or wherever it gets to. The Canadians' basic position is whatever level of reinspection we institute, they will follow. They would prefer to see none, but if we inspect 3,000 lots or 1 in every 20, or whatever the number works out to be, that is what they are going to do. If we do one in every five, that is what they are going to do.

Senator **Daschle**. Do they notify us which specific packages are going to be inspected?

Mr. **Zadjura**. No, because their process is done slightly different. They inspect at the point of destination. The truck is going to be unloaded anyhow, so they just select the samples there. They may have been preselected by computer, but when the trucks unloads, either the computer has selected this lot or this box, or whatever. So, when the truck is unloaded at destination, they do the inspection. So U.S. processors do not know ahead of time.

Senator **Daschle**. Well, that is a major advantage for them, would it not be? I mean, if we tell them this is what we are going to inspect, it then brings somebody up in Canada to the point of having to decide, well, here is some contaminated product, what do I do, do I pull it or do I just hunker down and face the music once the inspectors find this? That seems to me to be a very significant advantage for the Canadians.

Mr. **Zadjura**. Well, there is no doubt that the Canadian inspector is certainly in a dilemma because in his role representing Agriculture Canada, if he sees an obviously defective, bad piece of meat—and those are the cases where he can, let us say, see it because it is not frozen and boxed up—if he sees an obviously defective piece, as a Canadian inspector he is supposed to reject that. So, as a Canadian inspector, he is doing his job by rejecting it. He doesn't have to be cheating or there doesn't have to be anything under the table or anything like that; he is doing his job.

Senator **Daschle**. But the point is even though that individual inspector is in a dilemma, the country is at a distinct advantage to know ahead of time what products are going to be inspected.

Mr. **Zadjura**. Well, certainly, that would change whether or not you fail an inspection.

Senator **Daschle**. Absolutely.

Mr. **Zadjura**. If you substituted a good piece of meat and it then passes our inspection, you wouldn't stop the next 15 trucks coming from that plant.

Senator **Daschle**. That is right.

Mr. **Zadjura**. So it does circumvent the system. It would also, of course, distort your rejection rates on the presumption that the Canadian inspector is doing his job. If he sees a bad piece of meat and discards it from the sample, the rejection rate may, in fact, be higher than 3 percent.

Senator **Daschle**. But you do agree that it is a Canadian advantage to be notified in advance of what product is to be inspected?

Mr. **Zadjura**. Well, certainly, if you wanted to somehow impact the rejection rate, it would give you an advantage, obviously, if we are telling you——

Mr. **Harman**. If your objective is to impact the results—I mean, the way you are stating your question, it seems like there is a presumption that there is some effort on the part of the Canadians to impact that rejection rate. And if that were the objective, then, yes, that would give them an advantage to do that. They could very easily do that.

Senator **Daschle**. Well, I don't know what their motivation is, but it really doesn't seem to me to matter whether they are motivated in that regard or not. If, in fact, one side must notify and the other side is not required to notify, regardless of motivation, it seems to me you have a distinct advantage on the side that does not have to notify.

Mr. **Harman**. The controls are much better for the Canadian system.

Mr. **Zadjura**. Plus, I think, you have to look at that, Senator, really the other way from the consumer's point of view. We are at a big disadvantage if, even because of the best motivations, because he is a Canadian inspector doing his job—if he removes a defective sample, because that is his job in Canada—never mind that he is picking these samples for the United States. His job in Canada is to throw out bad meat.

If he is doing his job, he therefore throws out bad meat. It certainly increases the possibility that it will be missed on inspection here because the lot will go through, and the lot may have other bad meat or bad product.

Senator **Daschle**. That is right.

Mr. **Zadjura**. And it certainly increases the risk of getting bad meat or bad product here. It is a problem from a statistical standpoint of how it is being done because there is the potential of everything from unintended bias and the Canadian inspector doing his job to obviously, if somebody wanted to distort the system, they could either substitute good lots for bad, or vice versa, if they wanted to cause trade problems or health problems—substitute bad lots for good.

Senator **Daschle**. Well, I made reference a minute ago to the legal, procedural and administrative ramifications here. I would say that the legal ramifications concern me the most simply because I think we are getting into untested waters here that have broad ramifications in future years if the GATT Agreement would come to any conclusion. But, regardless, the safety question alone makes me very concerned.

Even if we could assume that the legal basis for what we are doing is adequate, we are basing it on a faulty assumption. That assumption is that equivalency can be documented, and what you have told me this afternoon verifies my own appreciation of the fact that we don't have adequate verification of equivalency today.

And even if that were right, the fact that we don't have verification of whether we are living up to that equivalency is perhaps the last straw. So you have three levels of vulnerability, if you will—the legal one, the equivalency or procedural one, and certainly the administrative one.

But what I would like to do, if I could, is ask you to stay until we have completed. We may want to bring you back for resolution of some questions that still have yet to be asked.

Mr. **Harman**. That would be fine.

Senator **Daschle**. I thank you very much.

Mr. **Harman**. Thank you.

[The prepared statement of Mr. Harman appears at the conclusion of the hearing.]

Senator **Daschle**. Mike Copps is the next witness. He represents the American Meat Institute. Mr. Copps, if you would come forth, we will take your testimony at this time.

Welcome.

Mr. **Copps**. Thank you.

Senator **Daschle**. As always, we are delighted to have you. We invite you to proceed as you wish. The entire text of your prepared statement will be made a part of the record.

STATEMENT OF MICHAEL J. COPPS, SENIOR VICE PRESIDENT, LEGISLATIVE AFFAIRS, AMERICAN MEAT INSTITUTE (AMI), WASHINGTON, DC; ACCOMPANIED BY JOHN GOULD, AMI MANAGER OF INSPECTION SERVICES

Mr. **Copps**. Thank you, Senator. I will be relatively brief. With me today is John Gould, who is AMI Manager of Inspection Services. We very much appreciate this opportunity to present our views to you.

BOTH THE UNITED STATES AND CANADIAN LIVESTOCK AND MEAT INDUSTRIES MAINTAIN A HIGHLY COMPETITIVE, PRODUCTIVE TRADING RELATIONSHIP

Both the United States and Canadian livestock and meat industries maintain a highly competitive, productive trading relationship. Canada is one of our largest export markets for U.S.-produced meat products. Last year, the United States exported to Canada beef, pork, lamb and poultry worth $360 million. At the same time, the United States imported from Canada $564 million worth of red meat and poultry products. Total weekly cross-border trade in red meat and poultry approaches $18 million.

THE BALANCE OF MEAT TRADE FAVORS CANADA ON PORK AND THE UNITED STATES ON BEEF, LAMB AND POULTRY

The balance of meat trade favors Canada on pork and the United States on beef, lamb and poultry. Even though we are a net importer of Canadian meat products, the close proximity and market similarities make Canada one of our most valued trading partners. Any development that has the potential to enhance trade between our two countries, such the free-trade agreement, is of utmost importance to the meat industry.

AMI BELIEVES THAT THE OPEN BORDER EXPERIMENT DESERVES A FAIR CHANCE TO WORK, WITH THE PROPER OVERSIGHT

AMI believes that the open border experiment deserves a fair chance to work, with the proper oversight. Our U.S. inspection system is more similar to Canada's meat inspection system than to that of any nation in the world. Each country's inspection program is staffed by professional veterinarians and meat inspection specialists who are fully capable of performing a neutral, third-party inspection on behalf of all customers.

IT IS IMPORTANT TO UNDERSTAND CLEARLY THE SCOPE OF THE OPEN BORDER PROPOSAL

It is important to understand clearly the scope of the open border proposal. All meat and poultry products will continue to be inspected by the respective government agencies.

Senator DASCHLE. Mr. Copps, let me stop you there. That isn't my understanding based on what the Department said and what GAO said. There will not be any inspection of imported product by our inspectors.

Mr. COPPS. No, but the reference here is that each country continues its inspection regime, rigorous inspection by systems which we think are comparable, if not equivalent.

Senator DASCHLE. So you are making reference to the fact that it is inspected by foreign inspectors?

Mr. COPPS. Yes, sir.

IMPORTERS WILL BE REQUIRED TO OBTAIN ADVANCED APPROVAL OF LABELS FOR MEAT AND POULTRY CONTAINERS FROM FSIS' STANDARDS AND LABELING DIVISION

Importers will be required to obtain advanced approval of labels for meat and poultry containers from FSIS' Standards and Labeling Division. All Animal and Plant Health Inspection Service requirements to control animal diseases, all Food and Drug Administration requirements to approve animal drugs, and all U.S. Customs requirements concerning duties, tariffs or other trade-related matters will remain virtually unchanged.

This means rigorous inspection will continue under existing health and safety standards. U.S. laws and regulations will apply to Canadian products entering U.S. commerce. Only *reinspection* at the border of previously inspected products will be discontinued.

Incidents will arise where product is determined not to meet the importing country's regulatory requirements. Similarly, respective product standards may occasionally vary according to the special needs of the importing country. The use of certain animal drugs and random sampling for illegal residues are often cited as examples.

It is important to remember that not all U.S. and Canadian production, processing and inspection requirements are identical. Nevertheless, each country's system is designed to produce safe and wholesome products.

PROBLEMS SHOULD NOT BE VIEWED AS AN INDICTMENT OF THE ENTIRE SYSTEM

Occasionally, problems can occur within any jurisdiction, but they should not be viewed as an indictment of the entire system. As problems are identified, AMI believes that they must be quickly and effectively addressed.

To that end, AMI and our Canadian counterpart, the Canadian Meat Council, have proposed a bilateral panel to monitor meat and poultry inspection during this experiment with open border trade. The panel would be government-appointed and comprised of industry, consumer, and government representatives. It would be commissioned to evaluate, on an ongoing basis, the 1-year trial, identify problems as they develop, and at the end of the year recommend how a permanent bilateral inspection program could be implemented.

The panel would oversee the tests and properly evaluate the results to assure that both countries maintain the highest standards for safety and wholesomeness of meat and poultry imports. Additionally, the panel would provide a necessary mechanism to address complaints and provide a repository for feedback on how the proposed system is working to protect public health. We envision this bilateral panel working hand-in-hand with the existing governmental Meat, Poultry and Egg Inspection Working Group that is commissioned to implement the broader precepts embodied in the free-trade agreement. But our proposal goes beyond that, and I think it can be helpful in maintaining the confidence that has been so much a part of this hearing today—consumer confidence.

Our objective is simple: free and fair trade of safe and wholesome meat and poultry products between the United States and Canada. If we can make free trade work between the United States and Canada, free trade with other countries becomes a more realistic possibility. But maintaining public confidence in our respective inspection systems is the necessary prerequisite to achieving that goal. We believe the panel we are proposing will help us in that regard.

Mr. Chairman, I will submit the rest of our statement for the record, but that is the crux of what we wanted to propose to you today.

Senator DASCHLE. Thank you, Mr. Copps. Let me ask you this. Has anything you heard today shaken your confidence about the current proposal?

Mr. COPPS. Well, I think much of the discussion centered about areas where we don't really feel competent to comment professionally, such as the legal aspects and all. I think that is going to be something for the Congress to work out. I think on the basic substance of it, we are confident with our basic conclusion that we need to test this proposal with proper oversight; that it has potential; that the systems between our two countries are sufficiently comparable to make it work. If it is not going to work between the United States and Canada, it is never going to work between anybody.

Let us give it a chance, but not just pell mell down the road with no checks and balances. Let us monitor every step of the way. Let us look for problems as they develop. Let us raise the flag if they do, and at the end of the day let us try to get on with a system that, number one, assures the confidence of the consumer in our meat supply, but, number two, moves us a little bit closer toward the world of free trade that we all talk about.

Senator DASCHLE. The equivalency question—you have obviously given a lot of thought to it. Judging from your statement, you have come to the conclusion that there is equivalency in inspection between Canada and the United States.

Mr. GOULD. Senator, could I address that? I worked at the USDA for several years in the enforcement area, and I am somewhat surprised that there is a question about equivalency with Canada. Obviously, I did not participate in reviewing the foreign country programs, but I know a lot of work went into it and it was an awful lot of work with foreign countries to determine that they had equal inspection programs.

Granted, after I left, they started changing the points of what they wanted to do on reviewing a country, and I was surprised to hear that they may have exempted approaching that with Canada. I don't know the reason why.

My dealings in the enforcement area of USDA with Canadian officials were very professional and very upbeat, and people wanted to enforce their laws the same as we attempted to enforce U.S. laws. So it is a surprise to me that there is a great concern about equivalency in Canada.

Senator DASCHLE. I am not sure I understand the basis of your surprise. Is it that they have set a somewhat different standard for Canada? Is that what you were surprised at?

Mr. GOULD. No, no.

Senator DASCHLE. You are surprised that there is any concern about equivalency?

Mr. GOULD. I am surprised that there is any concern about it because over the years I always felt from my own personal experience—I at one time was an import inspector and examined meat coming in from foreign countries, including Canada, and Canada seemed always to be on the spot. There are problems going both ways. If you look hard enough, you are going to find hair or blood clots in certain situations.

Senator DASCHLE. Well, did it surprise you—I was frankly a little surprised that there didn't seem to be an appreciation of what differences existed. I mean, there doesn't seem to be a tangible delineation of their standards and ours by which one can make an objective analysis.

Mr. GOULD. That surprised me that the Department didn't have that to furnish to GAO.

Senator **Daschle**. Yes. That is what I——

Mr. **Gould**. Yes, that surprised me that it wasn't there.

Senator **Daschle**. OK.

Mr. **Gould**. I would expect it would be there.

Senator **Daschle**. All right, very well. Thank you both.

Mr. **Gould**. One point I would like to make that was made earlier is we talked about spot-checking. The spot check that is proposed to be eliminated is at the border, and it was testified by Mr. Mark Manis that 75 to 80 percent of the meat coming into the United States is for manufacturing purposes. What that really comes down to is that meat will go to processing plants for the most part under USDA inspection.

Senator **Daschle**. But it isn't inspected at destination either.

Mr. **Gould**. It isn't inspected as——

Senator **Daschle**. As a Canadian product.

Mr. **Gould** [continuing]. As a Canadian product. It is inspected as a domestic product, and if it is found at that point to be unwholesome, unsafe, mislabeled, the inspector will be taking an action.

Senator **Daschle**. But, yet, no one will know at that point where it came from.

Mr. **Gould**. This is where the system of feeding back information so an evaluation can be made—that information has to be collected. You know, there was talk about destination inspection. For many years, we in the United States had destination inspection of Canadian products, and what that meant was the shipments of meat after they passed customs at the border went directly to packing plants. USDA inspectors made inspections as an imported product and made determinations should it be refused or entered. That was moved away from the plants to the border.

Senator **Daschle**. Let me ask you this. If I were a competitor, and I would imagine that you would consider—does AMI represent any Canadian processors, just out of curiosity?

Mr. **Gould**. Not that I know of.

Mr. **Copps**. No, sir.

Senator **Daschle**. You don't. You just represent U.S.—when we say American, we are not talking about Canadian at all?

Mr. **Gould**. Well, Americans have plants in Canada.

Senator **Daschle**. Oh, Americans do have plants in Canada?

Mr. **Copps**. Yes.

Senator **Daschle**. Oh, I see. Well, that puts a new light on things.

Mr. **Gould**. But there is an opportunity to export products. There are restrictions that Canadians have on U.S. packers that are uncomfortable.

Senator **Daschle**. So you are in a position of representing Canadian interests, frankly, as well as American interests.

Mr. **Gould**. Partly, partly. We have people who import and people who export to Canada.

Senator **Daschle**. Oh, I apologize. I made the assumption that was erroneous here. I would assume that when it comes to American interests on this issue—it would be interesting, among your members, whether there would be any difference of opinion. Frankly, I would think there would be a horrendous difference of opinion.

We have some plants in South Dakota, and I have to tell you if I was told that I am going to be inspected at destination in Canada when I ship up there, but I am not going to be able to determine which of those products are to be inspected prior to the time they reach my destination, but, on the flip side, they can send it here and we are going to tell them ahead of time what we are going to inspect, I tell you I would fill this room with people and I would be throwing things, I would be so angry. I mean, that is really an outrageous demonstration of competitive advantage, if you ask me.

And you are in a difficult spot because you are representing both sides here, and it puts you in a very precarious position in trying to say, well, this is what our members think, because your members are like my farmers. There are probably more opinions than there are farmers.

Mr. Copps. But they might be better served getting away from that regime that you are describing and going toward this new one, if indeed it is presently characterized by that much of a competitive advantage.

Going back to one other point that you raised, though, to what extent might our attitudes be changed as a result of what we heard here today. I think our basic thrust would remain exactly as we stated it. But I think if the sort of spot checks you and some of your colleagues were mentioning, be they of plants occasionally, or something—if a regime like that could be worked out, and apparently that is provided by the United States-Canada Free-Trade Agreement—if that would be something that would encourage and sustain the confidence of the Congress and the confidence of the people while this experiment goes on, it might well be worth looking into.

Senator Daschle. Why would you limit it just to while this experiment goes on?

Mr. Copps. Well, I wouldn't necessarily, but at the end of the day of this 1-year experiment, we are going to be hopefully looking toward what the permanent regime is going to be, and it could well be that that would be part of the permanent regime, too, sure.

Senator Daschle. Well, I appreciate it. You have really shed some light on this. I must say I think from our meat processors' point of view—and you speak for them; I don't, although I feel I do, but you do in an official capacity. I have to tell you I think we are getting the real short end of the stick on this thing, and that is obviously the purpose of the hearing. But we appreciate your contribution this afternoon.

Mr. Copps. We appreciate your contribution in holding the hearing.

Senator Daschle. Could you stay? Is that all right, Mr. Copps?

Mr. Copps. Sure, we would be delighted to.

Senator Daschle. OK, good.

Mr. Copps. Thank you.

[The prepared statement of Mr. Copps appears at the conclusion of the hearing.]

Senator Daschle. Our next witnesses are Kenny and Jim Schiltz, of Schiltz Foods in Sisseton, South Dakota. I would invite them to come forth at this point.

Gentlemen, welcome. We are pleased you are here. We know you have come a long way, and we invite you to proceed as you see fit.

STATEMENT OF KENNETH SCHILTZ, VICE PRESIDENT, SCHILTZ FOODS, INC., SISSETON, SD; ACCOMPANIED BY JAMES SCHILTZ

Mr. K. SCHILTZ. Well, Mr. Chairman, I would like to thank you for allowing us the opportunity to come to testify before this subcommittee. We have submitted written testimony and, with your permission, I would like to see it entered into the record.

Senator DASCHLE. Without objection, the entire text will be submitted for the record.

Mr. K. SCHILTZ. I would not go through all of our written testimony, but I would like to bring several points out.

Senator DASCHLE. OK.

WE HAVE SUBSTANTIATED SEVERAL DIFFERENCES IN THE GRADING BETWEEN USDA AND CANADIAN A GRADE PRODUCT

Mr. K. SCHILTZ. In our written testimony, we think that we have substantiated several differences in the grading between USDA and Canadian A grade product. The major differences that we see in our business are in the wings of the birds, the pin feathers that are left on grade A birds, Canadian, and——

Senator DASCHLE. What do you mean by the wings?

Mr. K. SCHILTZ. Well, in the United States, Senator Daschle, when a poultry processor in the United States wants to have an A grade shield on his bag, if one wing on the bird has a bruise, we have to, of course, cut that wing off or cut the portion of the wing off that is bruised. But then we also have to take the good wing, the remaining wing, and also cut that off.

Senator DASCHLE. You are required to cut both wings off even if one wing is bruised?

Mr. K. SCHILTZ. That is right. We cut both wings off so that to the consumer the product is a more balanced product.

Senator DASCHLE. The other wing is perfectly healthy?

Mr. K. SCHILTZ. The other wing is perfectly healthy, nothing wrong with it; it is wholesome.

Senator DASCHLE. But you are required to cut if off?

Mr. K. SCHILTZ. We have to cut it off.

Senator DASCHLE. And why again is that?

Mr. K. SCHILTZ. Well, it is a USDA regulation in the United States that if there would be a bruise on a wing tip or a bruise on a forearm, we must remove that bruise.

Senator DASCHLE. But what justification is there for requiring the other wing to be removed if there is nothing wrong with it?

Mr. J. Schiltz. It looks nice.

Mr. K. SCHILTZ. It makes the bird look better. This is for appearance, for grading. It makes the bird look more even, so we take both wings off.

Senator DASCHLE. So what do they require in Canada?

Mr. K. SCHILTZ. There is no requirement in Canada. They are allowed to leave the other wing on. Now, this may seem kind of insignificant, but in our business this amounts to about $10,000 a year that we have to cut off and throw away that our Canadian counterparts do not have to.

Senator DASCHLE. And they pass as Canadian grade A even though they wouldn't meet the U.S. grade A standard?

Mr. K. SCHILTZ. Yes. We have substantiated several instances where we have brought to the attention of our USDA grader, the graders that work in our plant, and we have brought them Canadian product labeled Canadian A and then they have graded this product and it has flunked their tests, the same tests that would be applied to our product.

PIN FEATHERS

Senator DASCHLE. You mentioned pin feathers. What is the difference in standard on pin feathers?

Mr. K. SCHILTZ. It is the same thing in regard to pin feathers, Senator Daschle. If we want our geese product to be labeled as grade A, the USDA grading requirement says that we must remove all pin feathers, hairs, or vestigial feathers that are visible to the grader upon inspection.

So if we want an A grade bird, we have to remove those pin feathers, even if it means sometimes we have geese that have pin feathers, we may have 50 or 60 or 70 people working off tables with penning knives and, one by one, pulling off those pin feathers. But this is a condition of an A grade shield.

Senator DASCHLE. So then what is the Canadian standard?

Mr. K. SCHILTZ. The Canadian regulations, as we see them, say they should remove the pin feathers. But, in fact, Canadian A grade birds are allowed to have lots of pin feathers left on them. Again, in two different tests that we did where we just went out on the street and bought Canadian A grade product and opened the product up, they have pin feathers on them and they don't seem to be required to remove those pins as we would be.

Senator DASCHLE. When it says grade A in a grocery store, if somebody walks in and they see grade A, is it clear somewhere on the label that it is Canadian grade A as opposed to U.S. grade A?

Mr. K. SCHILTZ. Yes, there is. In the United States when we have an A grade shield, it says USDA grade A. On a Canadian bag, it says Canada A. But we believe, and our distributors tell us, that the majority of American consumers think an A is an A. If it says USDA or Canada, whatever, an A grade is an A grade.

EQUIVALENCY

Senator DASCHLE. Especially if you have officials who say they are equivalent. We have had Department of Agriculture officials today say that they are equivalent. So you would have to assume if you were a consumer—I have just heard on television this high official in the Department of Agriculture tell me that their inspection is equivalent.

Now, I go and I have a choice of buying a Canadian grade A at 79 cents a pound and I see U.S. grade A at 89 cents a pound. And I am thinking, well, if they are equivalent and I can buy the Canadian grade A at a dime less per pound, I am going to go do it.

Mr. K. SCHILTZ. That is part of our problem, Senator Daschle. This has been going on for about 6 or 7 years now where the Canadian geese have been allowed to come into the U.S. market. We have been complaining to our USDA people, our inspectors, our graders, everybody in USDA that we could get to listen to us. But the standard answer that we get from our USDA is that this is what is in our requirements; if you want to pack an A grade goose, you do it the way it is in the requirements. So our standard answer is if you are going to make us do it, why don't you make our competitors do it?

RECIPROCITY ISSUE

Senator DASCHLE. Let me ask about the reciprocity issue. You know, it is one thing for you to have to deal with standards that are not the same, but I would have to assume access is the same—their access to the United States, your access to Canada. How much luck have you had with access in the Canadian market?

EXCHANGE RATE

Mr. K. SCHILTZ. We have never sold a single goose in Canada. We have tried to sell our geese in Canada, but part of the problem, Senator, is the difference in the exchange rate. The Canadians have enjoyed a difference in exchange rate.

To give you an example, I am not sure, but I think the exchange rate right now is about 17 percent, and that has ranged like 3 or 4 years ago up to almost a 40-percent difference. But let us assume that we wanted to sell our geese for $1 U.S. If that was what I wanted to net was $1 U.S., today if I wanted to sell our product in Canada I would have to ask for $1.16 Canadian to convert it back to receive that same $1 U.S.

Canada, on the other hand—if we are asking for $1 U.S. here, they can out-sell us based on the exchange rate. They could sell their product for 16 percent less in U.S. funds, take the U.S. money across the border and change it back into Canadian, and they have gained 16 percent on the value of the money.

Senator DASCHLE. So you are saying, aside from the whole inspection issue, the economic consequences of the exchange rate difference put them at a very distinct advantage?

Mr. K. SCHILTZ. Well, that is one part of it, the exchange rate, and the other thing that we have never been able to get past is in talking at different times to Canadian distributors, we asked them if they would be interested in purchasing our geese for resale or selling in Canada, and they laugh and they say no, there is no way you will ever get approval. So we ask them why and they say in Canada, if there are packers in Canada already producing the product, the Canadian Government just wouldn't give us an approval.

They will come up with enough things wrong with our plant or with our procedures. Officially, they probably would not say why, but unofficially they will find something wrong with our plant to keep us out. And since there are goose packers in Canada, we have very little hope, we feel, of ever selling geese in Canada.

Senator DASCHLE. But the whole spirit of the United States-Canada Free-Trade Agreement is to give equal access to both markets.

LET US HAVE FAIR TRADE

Mr. K. SCHILTZ. Well, it is, Senator Daschle, and we welcome the free-trade agreement, but let us have fair trade. Let us have free trade with Canada, but finally, after 6 or 7 years, let us have some fair trade. Let us have the Canadians read out of the same book that we do.

Really, this whole issue is sounding so complicated. We deal with the USDA every day when we are running our processing plant, and I can tell that if we were going to expect to send our product to Canada—if the Canadian Government told us, if you want to send product to our country, we are going to send our inspectors down to inspect it, that would make perfect sense to us.

If we were going to sell to Canada and they wanted to send their Agriculture Canada inspectors and their Agriculture Canada graders right into our plant, we would be happy to have them come, and we would pay for them just like we pay for our graders now. That is another point I might add. If we want USDA grade A on our poultry products, we have to pay the U.S. Government to send a certified grader to our plant.

Senator DASCHLE. Are you saying that the Canadians don't pay for their inspection?

Mr. K. SCHILTZ. The Canadians get an A grade shield on their bag and they don't have to pay the inspector. That is part of their inspection. That is maybe a small item, but it is another $10,000 a year or so that we have to pay that they don't.

Senator DASCHLE. I am going to ask the GAO and the Department of Agriculture about that. I thought there was some responsibility on the part of the processors, but you are saying there is not.

Mr. K. SCHILTZ. In the United States, Senator, for basic inspection, for inspection for wholesomeness, the USDA provides the inspectors for us up to 8 hours a day and a normal 5 days a week. If our inspectors work overtime or are on holiday or special days, then we have to reimburse the inspection. Grading, on the other hand, is voluntary. So if we want a USDA grader, we have to pay all of his wages.

Senator DASCHLE. So you differentiate between graders and inspectors. Graders are paid for by the processor.

Mr. K. SCHILTZ. That is right.

Senator DASCHLE. But they are not paid for in Canada?

Mr. K. SCHILTZ. No. It is our understanding that the Canadians do not pay for the grading; it is all rolled into one. So, that is another advantage that the Canadians do have.

THREE MAJOR DISADVANTAGES

Senator DASCHLE. So you really have three major disadvantages from a competitive point of view. First of all, you have inspection requirements that you have fairly clear evidence here that are not equal. I mean, pin feathers and wings are two illustrations of the inequality in inspection standards. That is number one.

Number two, you have a currency exchange rate difference that provides a very clear advantage to the Canadians.

Number three, with regard to grading and inspection, you have to provide, at least for the grader and overtime for the inspector, the payment, where in Canada processors have been able to avoid that.

Mr. K. SCHILTZ. It is our understanding that the Canadians don't pay for the grading the way we do.

Senator DASCHLE. That is incredible.

Mr. K. SCHILTZ. There are some other differences as well, in regard to the competition from the Canadian product. The thing that is very disheartening in our industry to us is that, I will tell you, we have very good USDA inspectors in our plant. Those fellows know what they are looking for. I have absolutely no doubt that our USDA people are assuring that we are putting out a clean, wholesome, properly graded product, and they make us jump through hoops to do that. Our graders can spot a defect from a country mile. They are experts at their job.

QUESTIONABLE GRADE A CANADIAN GEESE COMING INTO THE UNITED STATES

But at the same time there are so-called Canadian A grade geese coming into the United States, and we have told the USDA repeatedly, and showed them examples, but they continue to let this product come in. I really get to the point where we are wondering if USDA doesn't want any goose plants in the United States. It almost looks like they are trying to put us out of business. You know, I am a slow learner, but after 6 or 7 years I am kind of getting that feeling.

Senator DASCHLE. Well, very good. I am just going to ask you to stay where you are at because we only have one more witness, and then I would like to get a discussion on some of these points. I want to thank you both for coming and for offering your testimony this afternoon. It has been very helpful.

Mr. K. SCHILTZ. Thank you for allowing us to come, Senator.

[The prepared statement and attached exhibits A–G of Mr. Kenneth Schiltz appear at the conclusion of the hearing.]

Senator DASCHLE. Glenn Muller represents the National Pork Producers. Glenn, we are delighted you are with us. I would ask you to come forth at this point and give us your testimony. The full text of your prepared statement will be made a part of the record. I invite you to proceed as you see fit.

STATEMENT OF GLENN MULLER, PRESIDENT, SOUTH DAKOTA PORK PRODUCERS COUNCIL, DAVIS, SD, ON BEHALF OF THE NATIONAL PORK PRODUCERS COUNCIL (NPPC)

Mr. MULLER. Thank you, Mr. Chairman. I, too, would like to thank you for the opportunity to testify before you concerning the meat and poultry inspection agreements between the United States and Canada. I am Glenn Muller and I raise hogs on my farm near Davis, South Dakota. I am also currently the president of the South Dakota Pork Producers Council.

Today, I speak on behalf of the National Pork Producers Council (NPPC), which represents nearly 100,000 pork producers and their families in 45 States that are affiliated with the national organization.

WE APPLAUD YOU FOR HOLDING A HEARING ON THE PENDING PROPOSAL

We applaud you for holding a hearing on the pending proposal to establish an open border for meat and poultry trade between the United States and Canada. This hearing is extremely timely in light of the recent publication of the proposed implementing regulations in the Federal Register on June 29, 1990, and the release of a General Accounting Office report on this issue on July 6, 1990.

HEARINGS SUCH AS THIS HELP ENSURE THAT THE PUBLIC'S BEST INTEREST SUPERSEDES ALL OTHER GOALS

Hearings such as this help ensure that the public's best interest supersedes all other goals. NPPC is vitally interested in this border inspection program because Canada shipped 629 million pounds of hogs, along with fresh, chilled and frozen pork, to the United States last year.

THIS PROPOSAL TO ELIMINATE BORDER INSPECTION MUST ACCOMPLISH TWO IMPORTANT TASKS

This proposal to eliminate border inspection must accomplish two important tasks. First, it should allow for the continuation of a safe food supply for all people. This is NPPC's highest priority. Second, the proposal can allow the United States and Canada to test new trading arrangements. This program can serve as a laboratory for many future agreements that will benefit U.S. citizens as well as pork producers by encouraging the U.S. economy with more export opportunities around the globe.

FOOD SAFETY ASSURANCES

The United States has developed one of the best meat inspection programs in the world. The similarity of our program to Canada's should help increase our confidence that consumers will receive safe and wholesome meat products.

However, we do not believe that the Food Safety and Inspection Service (FSIS) should in any way abrogate its responsibility or efforts to assure maintenance of equivalency in our two meat inspection systems. Point-of-destination inspections will help provide a safeguard that Canadian product is acceptable. But it may prove inadequate over time if we don't take advantage of opportunities to monitor the Canadian inspection system at point-of-origin in Canada.

As I mentioned previously, providing a safe food supply is NPPC's leading concern. The wholesomeness of the food supply must never be sacrificed in the name of free trade.

Nor should we allow the reputation of U.S. pork producers to be tarnished by permitting poor quality or unwholesome meat to reach the public's plates. Under this new program, American consumers will not be able to tell the difference between most of the pork that will enter this country from Canada and domestically produced meat.

The GAO report raises some valid questions concerning unexplained rejection rates for Canadian meat products in 1989. We believe that it is imperative for us to critically assess the current status of the Canadian meat inspection system before we wholly accept and embrace their system as sufficiently equivalent to our own. As stated by GAO, "we believe FSIS needs to clearly demonstrate and document that American consumers can rely on the Canadian inspection system to guard against contaminated meat under an open border."

Our own U.S. pork producers are working diligently to make sure that their meat is free of drug residues through our Pork Quality Assurance Program that we launched in June of 1989. Currently, we have more than 15 million hogs, or about 18 percent of the U.S. annual production, are now produced by farmers enrolled in this program. These producers are going through a verification program stating that they themselves are using drugs properly, abiding by drug withdrawal times, and more. We believe this effort demonstrates our commitment to a wholesome food supply.

Because of our emphasis on food safety, we ask that the new inspection program's 1-year trial period also be a period of intensive review. During the 1-year trial, USDA should periodically conduct thorough reviews of the program for any residue or other food quality problems. To facilitate this, USDA should closely monitor packing plants in Canada and point-of-destination inspections.

We encourage USDA to appoint a panel of industry, consumer and government representatives to assist in evaluating the 1-year trial program. Such a panel could use its expertise to help make sure that every step is taken to make the inspection program succeed. The presence of an oversight panel should also increase consumer confidence in the new border inspection agreement. They could also provide guidance in establishing a permanent bilateral inspection program between the United States and Canada. On the other hand, such a panel should not be used to replace day-to-day inspection functions or oversight responsibilities of FSIS.

NPPC understands that Canada permits the use of two drugs that are not approved in the United States. In Canada, the products, Dimetridazole and Ipronidazole, are used to treat livestock and poultry diseases. Yet, our own Food and Drug Administration has not approved the products, and it is believed that they may cause cancer. Because of the questions associated with these drugs, NPPC believes that Canada should discontinue the use of these drugs. In the interim, USDA may need to implement routine testing procedures for residues from Dimetridazole and Ipronidazole in the imported meat supply.

IMPLEMENTATION OF AGREEMENT

GAO also raises questions concerning the legal authority to proceed with implementing the open border inspection system. These issues will need to be resolved, along with the physical details of how this new process will work.

It may be appropriate for FSIS to conduct a briefing to outline the details of the system as proposed in the implementing regulation.

CONCLUSION

Again, I would say NPPC is appreciative for the opportunity to provide these views on the proposed meat and poultry inspection agreement between the United States and Canada. Please feel free to call on our organization if we may provide further input or assistance on this significant change in meat inspection between our two countries. We look forward to working with our Canadian neighbors in the development of a meat inspection program that assures U.S. and Canadian consumers that the food they eat is the safest in the world.

Thank you.

[The prepared statement of Mr. Muller appears at the conclusion of the hearing.]

Senator DASCHLE. Thank you very much, Glenn.

Let me ask the witnesses to come back to the table now for just a final discussion for a couple of minutes and then we will close out the hearing. I appreciate everybody's tolerance of time and your contribution today. It has been a very informative session.

LEGALITY OF DRUGS

Mr. Manis, let me just start with you. You have heard testimony now this afternoon with regard to some practical experiences in day-to-day marketing in Canada. Mr. Muller just indicated that from a pork producer's point of view, you have two drugs, Dimetridazole and Ipronidazole, that are legal in Canada that are not legal here.

Number one, it would appear to be a competitive disadvantage for our producers versus the Canadian producers. They are being used for whatever reason. But, secondly, there is a safety question involved from the consumer's point of view.

So from both safety as well as competitiveness, it would appear that we are at a very distinct disadvantage unless we would stipulate in some way that the same regulations apply in their country that apply in ours. Isn't that a reasonable conclusion?

Mr. MANIS. It certainly is a significant question. I guess one way of addressing it would be that that is an issue that is aside from this proposal for a 1-year experiment. In other words, that difference is currently in place under border inspection. So, in effect, that is not an issue that is part of our proposal.

Senator DASCHLE. But let me differ only in the extent—and I don't mean to interrupt, but part of this proposal is using as its basis an appreciation of equivalency in inspection and standards. And if, clearly, there is not equivalency in the utilization of drugs—maybe it is a growth hormone. I don't know what it is, but if that equivalency doesn't exist either from a safety point of view or a production point of view, wouldn't that be a significant factor in undermining the very premise upon which this agreement is based?

Mr. MANIS. The premise being equivalency?

Senator DASCHLE. That is right.

Mr. MANIS. The issue of use of drugs between one country and another extends beyond Canada and the United States. In other words, it is a difficult issue for us in a diplomatic sense in terms of what drugs can be used in another country and what cannot.

Our position is, of course, if those drugs and others can't be used in the United States, conversely there are drugs that we use that other countries do not allow. So it is a complicated question.

Senator DASCHLE. But for purposes today, we are only limiting our concern to Canada.

Mr. MANIS. That is fine.

Senator DASCHLE. Right.

Mr. MANIS. But it is a broad question is my point, that it extends beyond Canada.

Senator DASCHLE. I understand that.

Mr. MANIS. Broadly speaking, the answer is that we find we allow the use of drugs that other countries do not permit, and we are aware of that particularly with the European Community and that is an issue that is of contention.

The way we deal with it is that we say that if this product is to come into the United States from another country, that type of animal drug cannot be used. So it is hard to say, simply, these are the drugs we permit and these are the only drugs you, country *x*, will permit, Canada or otherwise. So we don't deal with it in that fashion, although there are attempts in international conferences to try to resolve that question.

But, granted, it is a difficult question, and I don't think there is any doubt about that. My point is that it extends beyond Canada. It extends to drugs that we can't use that others say——

Senator DASCHLE. But the only place where it is relevant for our purposes today is with Canada because it is the only country with which we have a free-trade agreement, and we are saying with the free-trade agreement all our other considerations are off the table; I mean, we are going to accept your product.

And one of the major arguing points that we made in passing the United States-Canada Free-Trade Agreement is equivalency; it is equivalent. Well, now we have two examples when it comes to drugs when equivalency is clearly undermined and it just doesn't seem sufficient to say, well, we are trying to work that out in a global context.

You have producers here who are told they can't use those drugs. You have a basis upon which we have made that decision, either safety or some other factor. But how, in the context of a free-trade agreement, can we allow that to happen?

Mr. MANIS. I think there is another issue here as well in that for the Canadians to export product—the nitrite issue came up earlier—it has to meet our standard. Today, we test products for nitrites, and we test based upon a threshold level of the U.S. standard, not any other country's standard. So the presumption, of course, is that it will have to meet our standard, and we would expect that to be the case and continue.

Senator DASCHLE. But how do we know? We are not going to be able to verify. We have already stipulated—I mean, in our testimony today it has been brought out that there is no verification.

Mr. **Manis**. Under the proposal for the experiment?

Senator **Daschle**. That is right.

Mr. **Manis**. That is, on its face, true. The fact is, though, that we would expect Agriculture Canada to be cognizant of the standards in the United States, and that a plant that wants to export a product with a given component such as nitrites would have to meet that standard. In other words, what we are saying is that we have confidence in that Government's inspection system to say that that is the case.

Senator **Daschle**. But how do we verify whether that confidence is legitimate?

Mr. **Manis**. I think I indicated earlier that we are exploring different ways of verification that would be necessary because of the changes proposed with a bilateral group that would explore the issue of equivalency further. You did raise the point, "why now?" Well, because we are making changes. So in other words, we are factoring in some changes to appoint such a group, with scientists respected from both sides, that would explore those sorts of issues.

Senator **Daschle**. Let me ask anybody in the GAO, from your appreciation of the study you have just completed, is this or is this not considered somewhat of a competitive disadvantage for producers?

Mr. **Harman**. It could be. As he just said, it depends on how well Canadians would do their job. It is not a competitive disadvantage if they do the job and their system is equivalent to ours and we are confident in that and they can detect these substances. Then there is no competitive advantage.

Senator **Daschle**. What you are saying is if the Canadians themselves mandate to their processors that if they are going to export to the United States they can't use nitrites at the level that they are prohibited in this country, or these chemicals or any others, and they verify that that is the case in their inspection system, then it is no disadvantage?

Mr. **Harman**. That is correct, but if it is not, then there definitely would be an advantage in any of these situations.

Senator **Daschle**. And I guess everyone at the table agrees that under the current proposal we would have no way of verifying whether or not Canada is living up to its responsibility in that regard.

Mr. **Harman**. As I understand it, it seems like that has been brought out any number of times.

ISSUE OF STANDARDS—GRADING

Senator **Daschle**. Right. Let me deal with the issues that were raised by the Schiltz's. First, with regard to standards in geese, wings and pin feathers, is that your understanding, as it was presented? Let me ask anybody from the Department to elaborate?

Mr. **Golden**. Senator, I think that maybe the witnesses that have been here from USDA are at a disadvantage on this issue. I am at a different kind of disadvantage. This is an Agricultural Marketing

Service program. It is not conducted by the Food Safety and Inspection Service.

The grading program is a voluntary program that is funded on a user-fee basis in the United States, and it is conducted by the Agricultural Marketing Service. I believe, although I am not certain of this, that in Canada it is an intrinsic part of the inspection service, and that is why there is a difference between the—and it is mandatory there, while it is voluntary here, and that is the rationale behind the fact that it is not charged against producers in Canada. I think the facts that were stated at the table are correct as far as I know.

I think we have some additional information.

Mr. Manis. I am familiar with the situation that Mr. Schiltz has testified to. The issue here with respect to the geese is not a safety issue. It is an aesthetic issue in terms of grading. The safety issue is what this agency, FSIS, is responsible for, and there is no charge for that inspection during an 8-hour day.

Nevertheless, there is overlap because FSIS approves the labels, and the Canadian geese coming in are labeled "Canada A." So while it is a grading service question of acceptability of standards for the Canadian A, there is overlap with respect to FSIS approval of the label.

Last year during the period of time that geese are consumed, holiday time, we became aware of the issue that Mr. Schiltz has brought to your attention, the issue being whether or not the Canadian geese were in grade. As a result of inquiry and concern on his part, we then proceeded to stop all shipments to check for the grade applicability on Canadian geese. They all happened to come through North Dakota. That exercise was carried out and one load was turned back because the geese were out of grade.

What then came to light is that there was a difference in application of the standard between the two grading services, and it is the issue of the wings and the symmetry. At that juncture of last year in the winter, we were checking each load and our inspector was cross-utilized—FSIS' inspector was cross-utilized through the grading service to check the birds. He did do that.

Since that time, Agriculture Canada grading officials and USDA grading officials have correlated and have resolved the differences as to interpretation of grade. Therefore, where we are at this point is what we will continue up until the time of the experiment.

In other words, if Canadian birds were to come down today, since we are not in the experimental mode and a product exam was assigned, we would check to verify that, in fact, the grading is similar. So we believe that essentially that issue has been looked at and handled, and was handled last year and will continue to be handled up to the point of the beginning of the experiment.

Senator Daschle. So when we were talking about the fact that we are now spot-checking, will that spot-checking continue for grading even though it won't continue for inspection if this agreement takes effect?

Mr. Manis. During the course of the experiment, at the point that we start the experiment, we will not do either health or aesthetic checking.

Senator Daschle. Well, then, how will we know?

Mr. MANIS. The answer to your question is similar to the answer to the question of how do we know about the safety issue. In other words, if a load of geese were to come today and it were randomly assigned an inspection, we would do the safety inspection. We would also check for grading purposes. Therefore, if we do not do that for safety, we will as well not do it for grade.

CURRENCY POINT

Senator DASCHLE. Does anyone at the table disagree with the conclusion that I draw from this testimony that from a currency point of view, seemingly from a standard point of view, as well as from the point of view of having to pay graders in this country, U.S. producers are at a distinct disadvantage from a competitive point of view? Does anyone disagree with that?

USDA INSPECTION

Mr. K. SCHILTZ. I would make one more point about the USDA inspection that we didn't bring out before, Senator. There is a big difference between USDA inspectors and USDA graders. Inspectors are trained by the USDA to check for wholesomeness and things like proper labeling and point of origin of the product. USDA graders are trained to look at the aesthetic qualities, at the physical appearance of the birds.

I believe, and to the best of my knowledge, up until Mr. Manis stopped a load of Canadian geese last fall on the border and had a USDA grader reject that load, I don't think there has ever been a time when a USDA grader graded geese or checked geese for labeling. What loads they did check, they had USDA inspectors check, and they are not trained in grading. So how could a USDA inspector determine whether it is a proper grade or not?

Senator DASCHLE. What is the answer to that, Mr. Manis?

Mr. MANIS. Mr. Schiltz is correct that our inspectors normally do not have responsibility for grading. Therefore, if, in years past—and, of course, we did—look at the geese, we would be looking for safety issues only.

However, at the point where we became aware of the concern that has come forward today, we worked with the grading service to have our person adequately trained by grading people so that he could be adequately knowledgeable to check for grade as well as safety.

Mr. K. SCHILTZ. Could we have that person come to our plant and grade our geese instead of the normal grader that you assign to us, or AMS assigns?

Mr. MANIS. I think I would have to defer on the level of expertise and training that occurred. In other words, when it comes to grading, we do defer to AMS, Agricultural Marketing Service, graders. And we were in concert with grading people, and I suppose our inspector was sufficiently trained enough to find a flaw in a load and send the product back. But our person in North Dakota is not a grader, and it was based upon an assessment from AMS that he would be sufficiently trained to conduct that activity.

Beyond that, it is correct that when we do inspection, meat or poultry, we are doing it for safety only and we do not reach out to the scope of grading for aesthetics. That is a correct statement.

EQUIVALENCY ISSUE

Senator **Daschle**. Very well. Let me see if I can clarify one last point as long as everybody is at the table, and that has to do with the equivalency issue again. I was under the impression, and maybe I misunderstood what was said by the Department earlier, that you believe the documentation to ensure adequate confidence about the equivalency of inspection standards is tangibly available; in other words, can clearly be presented in an objective way for evaluation.

The impression I had from what the GAO said is that that clearly is not the case from their perspective. The Department then said, well, we think it is adequate, but if they want additional justification, we have no problem with that. Is that a clear appreciation of the position currently held by the Department of Agriculture?

Mr. **Manis**. The issue of equivalency is a documentation issue and it extends beyond. So when we say that Canada is equivalent, it is based upon multiple factors that we have already discussed today, but it does include documentation.

We allowed the GAO entry into all of our files with respect to Canada, and they are large. I don't think it is a fair statement to say there is no documentation on Canadian inspection.

Senator **Daschle**. I don't think they were saying that. They were saying it isn't adequate.

Mr. **Manis**. We appreciate the fact that it could be better, and I think GAO has also testified that over time we have made improvements, or are attempting to make improvements.

Senator **Daschle**. By saying it could be better, are you saying that it currently then is inadequate?

Mr. **Manis**. No, no, we are not saying that at all. I think that there is a difference of perspective, and it is legitimate. We find this with our inspector general as well within the Department, critiquing the level of documentation of equivalency of other countries beyond Canada.

We are comfortable that we have documentation and that it is adequate and sufficient. Nevertheless, it is valid from an auditor's perspective to say that it could be better, and that is evidenced in the GAO report. We don't dispute that. For example, the report indicated that we did an experiment before implementing the free-trade agreement in 1989, and I was heavily involved with that.

Then it was asked, well, where is your documentation of the success or lack of success of the trial in October. Well, it wasn't there, and that is a legitimate point, so we could do a better job. But, nevertheless, as a line-functioning organization with finite responsibilities of inspection, granted, we could do a better job, but we feel it is adequate. The points are well taken. We will continue to strive to improve, to have a better audit trail.

Senator **Daschle**. Why wouldn't it make sense for us to say until the GAO and everybody is confident that equivalency is adequately documented, we are going to insist on verification, because it allows for that? Even the United States-Canada Free-Trade Agreement allows for spot checks, our own verification. Why are we opposed to that?

Mr. **Manis**. We are confident that Canada is equivalent. We have never suggested otherwise. I think the issue here, rather, is are we successfully, to the GAO's standards, documenting that equivalence. I think that is a different issue than whether or not the country is equivalent. I don't think the Department is saying that Canada is not equivalent.

Senator **Daschle**. But you admit that you don't have sufficient justification to document that equivalency?

Mr. **Manis**. No. What I am admitting is that I acknowledge that perhaps we could do a better job. I am not disagreeing with the GAO that that would be a wise thing to do, and I respect their perspective. But, nevertheless, it doesn't suggest that we either question the equivalence or question our ability to derive its equivalence. I really see two distinctions there.

Mr. **Harman**. Mr. Chairman.

Senator **Daschle**. Yes, Mr. Harman.

Mr. **Harman**. I think I see the distinction he is making, and I will let Ed talk a little bit here. I know the hour is getting late, and you can stop us if you like. There is no doubt, I think, in our mind that the FSIS believes that the Canadian system is equivalent, and it is based on a good deal of experience that they have had over the years in dealing with that system. There is just, I think, no doubt in their mind that it is OK.

But we come in questioning that and we are looking for evidence. We are looking for, well, what makes you think that other than "believe us." That is where I think we got into trouble, and I think our concern, as I said earlier, is not that you satisfy GAO as much as you are able to satisfy the Congress and consumer groups that may come in and question that if you run into a problem.

Now, I will let Ed talk a little bit about the kind of evidence we looked for and then what we found.

Mr. **Zadjura**. First, I would like to say this is based on some interviews with Mr. Havlik [William J. Havlik, International Programs, Assistant Deputy Administrator, Food Safety and Inspection Service], who I believe is the Deputy Administrator of FSIS' International Programs. One of the questions we asked him directly is how well documented is any information on the Canadian inspection system. His answer is basically that the infrastructure of Canada's meat inspection system is not well documented. Records documenting the Canadian meat inspection decision process, discussion with Agriculture Canada personnel, how Canada reacts to problems in view of Canadian laws and regulations and other infrastructure areas have not been well documented.

Further, he went on to tell us that it was their intent all along to do the comprehensive five-area risk assessment of Canada, but essentially events were overtaken by the free-trade negotiations. So their intent was to document this, to do the evaluations thoroughly, and it essentially, has gotten out of their hands.

Finally, we have gone through every one of their records, and I can provide you with a list of every single file that consists of basically one file drawer-and-a-half for the entire country of Canada for the years 1983 through the present.

Many of these files are reviews of individual plants, not of the Canadian inspection system, and this is a list of all the file folders, their titles and related information. One interesting example, I think, is a file drawer labeled risk profiles, 1986, and it contained the following information. Residues: results of Agriculture Canada sulfonamide program; two, disease, folder empty; three, growth contamination, folder empty; four, economic fraud, folder empty; five, additives, packaging, et cetera, folder empty; six, microbial contamination, folder empty; seven, contamination, folder empty.

You can call it inadequate documentation. I think that certainly fits the bill.

Senator DASCHLE. A pretty light file.

Mr. ZADJURA. And the current system, USDA's system for approving and determining equivalency for other countries, is simply not being followed for Canada. What they have done is make a determination by essentially sitting around a table saying we know this, trust us, it sounds good.

It may be perfectly equivalent, OK, but I submit that they are hard-pressed to show any evidence of that other than essentially "trust me." They can argue whether we are arguing documentation or not. There is just simply a lack of good, sustainable evidence that this determination has been made, has been effectively made, comprehensively made, and any other way you want to look at it.

Senator DASCHLE. It is pretty hard to argue, Mr. Manis. I mean, how do you respond to that?

Mr. MANIS. Well, in all fairness, Senator, I think that for the record we will have to respond in more detail. I don't have any data with me and we will be happy to respond to that statement for the record.

Senator DASCHLE. OK.

[The information referred to is retained in the subcommittee file. See letter on pp. 14–15, dated August 6, 1990, from Jo Ann R. Smith, Assistant Secretary, Marketing and Inspection Services, Department of Agriculture, Office of the Secretary.]

Senator DASCHLE. Any final remarks?

IMPACT OF THIS DECISION THAT WILL BE FELT BY THE PRODUCERS

Mr. MULLER. I just have one thing, Senator, that I would like to expand on a little bit, and that is the impact of this decision that will be felt by the producers. We are very concerned about quality assurance and delivering a wholesome, healthy product to our consumers. FDA has told us that the two drugs are considered to potentially contain carcinogens or create cancer.

We as domestic producers have been very conscious of that and have worked very hard to improve the image of our product and specifically, the pork industry. I am very concerned, and we as an industry are very concerned about any violations of this trust. Violations in the feed chain of the feed being fed to our product need to be traced back. That is why we supported the swine ID program.

We are also concerned about any violations or any drug residues entering the food chain to the consumers through an import basis because, as Senator Burns said earlier, we the producers are the ones that pay the price. And I think the alar situation in the apples serves as an example of that. It may not be a violation, but merely the perception of the possibility of drug residues entering the food chain through this import system could have a very detrimental effect on our industry. And I think it is the responsibility of the Food Safety and Inspection Service, and the government in general, to protect us from those violations, and that is very important as we consider this issue.

Senator DASCHLE. Thank you.

I want to thank all of our witnesses this afternoon. I have learned a good deal about the issue, and I must say we have had some excellent discussion and I think it has been enlightening.

I will again emphasize that we are going to submit this hearing record as a comment on the proposed rule. That will be made within the next couple of days. I will leave the record open for a day or so to ensure that anyone who has a statement has an opportunity to present it.

Congressman Johnson and Senator Leahy, the chairman of the committee, have statements and asked that I make sure that they be submitted for the record, which I will do at this time.[5]

The hearing stands adjourned.

[Whereupon, at 5:32 p.m., the subcommittee was adjourned, subject to the call of the Chair.]

EDITOR'S NOTE.—The following publications are retained in the subcommittee file:

Annual Report on Chemicals and Biological Testing for Fiscal Year 1988/89 (Agri-Food Supply Division, Food Production and Inspection Branch, Agriculture Canada);

Manual of Procedures, July 1988, Food Production and Inspection Branch/Meat and Poultry Products Division; and

Amendments to Manual of Procedures—Part A.

[Material submitted for inclusion in the record follows:]

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[5] See pp. 3-4 for the prepared statements of Senator Leahy and Congressman Tim Johnson.

APPENDIX

PREPARED STATEMENT OF JO ANN R. SMITH, ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE

Mr. Chairman and members of the subcommittee, I appreciate having this opportunity to testify before you today on USDA's plans for implementing the U.S.-Canada "Open Border" agreement for meat and poultry.

Before discussing the specifics of the Open Border agreement for meat and poultry, I would like to discuss the pact that fostered the meat and poultry agreement—the U.S.-Canada Free-Trade Agreement. As you know, President Reagan and Canadian Prime Minister Brian Mulroney signed an agreement on January 2, 1988 to end virtually all tariffs and most other restrictions on trade between the United States and Canada by 1998.

The U.S.-Canada Free-Trade Agreement could not be implemented until both the U.S. Congress and the Canadian Parliament approved the pact and passed legislation bringing a large number of domestic laws into conformity with the Agreement. As you know, Congress and Parliament both had lengthy debates over provisions of the agreement, but approval was ultimately granted before the agreement went into effect on January 1, 1989.

It is important to keep in mind the goal of the U.S.-Canada Free-Trade Agreement—to promote economic growth in both the United States and Canada By opening markets, our economies will prosper and our goods will become more competitive internationally.

It is also important to remember that the Free Trade Agreement operates for the benefit of both the U.S. and Canada. While Canadians will be able to export more products to the United States with fewer regulatory and tariff burdens, U.S. manufacturers and producers will also be able to export more products to Canada with the same lessening of restrictions and tariffs.

Most Americans support the concept of the Free-Trade Agreement with Canada, our largest trading partner. However, implementing the Agreement provides some challenges to both countries. The opening of our borders with Canada with respect to the importation and exportation of meat and poultry products will increase competition on both sides of the border, and it is certain there will be a period of adjustment before trade between the two countries reaches an ideal level.

OPEN BORDER AGREEMENT FOR MEAT AND POULTRY

As a result of the Free-Trade Agreement, there are adjustments to be made in the meat and poultry industry. The intent of the Free-Trade Agreement is to reduce the intensity of reinspection of meat and poultry moving between the United States and Canada. This provision is one of the first tests of whether the reality of the Free-Trade Agreement can, in fact, match the rhetoric of those who say they support free trade.

USDA and Agriculture Canada agreed in February 1990 to implement on a 1-year basis, an experimental open border agreement with regard to meat and poultry trade. Pursuant to notice and comment rulemaking, Canadian products to be imported into the United States will be inspected by Agriculture Canada and certified for export. Those products may then be imported into the United States without further reinspection by USDA.

The same is true for U.S. products. They will be inspected by USDA and certified for export to Canada. Agriculture Canada will not reinspect U.S. imports. USDA and Agriculture Canada have comparable inspection systems, registration, sanitation and label requirements, as well as residue testing programs.

An evaluation of this experiment will take place by the Meat, Poultry, and Egg Inspection Working Group, which was established by the Free-Trade Agreement. The evaluation will determine whether the open border experiment should be made permanent under the applicable law and the Free-Trade Agreement.

CANADIAN INSPECTION SYSTEM

It is important to note that neither the United States nor Canada will continue to maintain border inspection facilities.

The 1-year experiment for meat and poultry is feasible because the Canadian meat and poultry inspection system operated by Agriculture Canada is virtually identical to the U.S. meat inspection system operated by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). The two inspection systems also produce equivalent degrees of health benefits. Both programs are comprehensive and mandatory, and have been in existence since the early 1900's.

REGISTRATION

Canadian and U.S. slaughter and processing plants must register with Agriculture Canada or USDA if they ship products between provinces or States. Canadian and U.S. plants must also apply to Agriculture Canada or USDA if product is to be shipped out of the country.

Canadian meat plants that do not ship product outside of their province may be inspected under provincial programs. Requirements for plant licensing vary between provinces. The United States has a similar program for its States.

SANITATION

As part of the Canadian registration program, Agriculture Canada ensures that their federally inspected plants meet standards for plant layout and design, site selection, equipment, and sanitation programs. Agriculture Canada also approves all materials used in Federal plants, from construction materials to sanitizers, as well as new equipment and plant renovations. USDA also requires approval of its federally inspected plants' facilities, equipment, and procedures to make sure the operation will be sanitary.

INSPECTION

Agriculture Canada inspects all its federally registered meat and poultry plants. There are 1,400 qualified veterinarians and specially trained inspectors located in more than 800 slaughter, processing and storage facilities across Canada. In the United States, there are more than 7,700 Federal inspectors, food technologists and veterinarians who carry out Federal inspection laws in some 6,700 meat and poultry slaughtering and processing plants.

Federally inspected slaughter plants in both the United States and Canada are required to have a veterinarian or inspector onsite during plant operation to inspect every animal and carcass. Animals are observed on arrival at the plant and are inspected again within 24 hours before slaughter, or in the United States, they must be inspected on the day of slaughter. If veterinarians identify animals suspected of disease or unwholesomeness, those animals are segregated and laboratory tests may be conducted to verify their condition. If results indicate the entire animal is diseased or that violative levels of contaminants are present, the animal is condemned. Again, this is true under both the United States and the Canadian inspection systems.

Following slaughter, the carcass, internal organs and glands are separated and further tested. Diseased or contaminated meat is destroyed or sent to a rendering plant that produces inedible products. Meat carcasses passing inspection are stamped with an inspection symbol containing the word "Canada," or, in the case of the United States, "USDA inspected and passed."

Processing inspection in both countries is conducted on the basis of scientific evidence. Agriculture Canada and USDA monitor sanitary conditions and the critical steps in the processing operation. If the products or plant conditions do not meet established standards, the inspector may condemn or retain any or all products within a plant. If detained, meat or meat products will only be released for shipment once it has been verified that the meat is wholesome and otherwise not adulterated.

LABEL APPROVAL

Agriculture Canada must approve labels for all foods containing meat and poultry from federally registered plants and imports. All labels must include the name of the product, its weight and ingredients, the name and address of the processor and any refrigeration and handling instructions that might be required. The USDA label approval process and labeling requirements are essentially identical.

RESIDUE TESTING

Both USDA and Agriculture Canada have comprehensive residue testing programs for meat and poultry. In Canada, Health and Welfare Canada must approve all pharmaceutically based drugs used on animals. The Canadian Bureau of Veterinary Drugs evaluates results of toxicity, residue, pharmacological and clinical studies to determine a drug's safety and efficacy. It also sets guidelines for drug use, withdrawal periods, and tolerance levels for residues in foods. The Food and Drug Administration fulfills this role in the United States.

Agriculture Canada then monitors meat and poultry products for bacterial, drug, and chemical contaminants, just as USDA does. The presence of certain contaminants initiates followup procedures, which may include testing of feed, or other animals in the herd. The results of Agriculture Canada's residue testing are published annually by the Agri-food Safety Division.

INTERNAL REVIEW

Both the United States and Canada maintain internal review programs to ensure that meat and poultry products intended for export meet the laws and regulations of the respective countries. Both countries also review plants in the other country to ensure standards are maintained. If the standards are met, each country certifies individual plants as eligible to export to the other country. On occasion, plants have been reviewed that did not meet the reviewing country's standards. These plants have been delisted and are therefore prohibited from exporting product to the reviewing country. The inspection service in the reviewed country then takes action to correct the problem areas. If the problems are corrected, the plant may then be recertified for exporting.

Since both the United States and Canada have essentially identical procedures for reviewing their plants and for correcting problems, the new proposed rule will permit each country to deal with its own problems and, when necessary, prohibit exports without using the delistment process.

PROPOSED RULE

The 1-year open border experiment is presently embodied only in a proposed rule—not a final rule. We want you and your constituents to participate in this rulemaking process, and we welcome your comments. The rule was published in the Federal Register on Friday, June 29, 1990, and the comment period will run for 30 days. We intend to review those comments and issue a final rule as soon as possible.

The proposed rule is a result of the unique and special relationship between the United States and Canada. This unique relationship is based on several factors—the fact that the countries are contiguous to each other; that open border policies have been in effect for many years; and that there are no significant differences in animal health practices and the production and processing of meat and poultry products.

For a foreign country to export meat and poultry products into the United States, USDA requires that the foreign country's inspection system be "at least equal to" all of the provisions applicable to our inspection system and the production of domestic meat and poultry in the United States.

Unlike the majority of other countries' inspection systems, both Canada and the United States apply only one standard of inspection to products intended for domestic consumption and export. Most other countries provide one standard of inspection for domestic product and one for product intended for export.

Before issuing the proposed rule in June 1990, FSIS had published an interim rule on January 5, 1989, that exempted all Canadian product imported into the United States from being stamped with the official USDA mark of inspection. In addition, the interim rule authorized new "streamlined" reinspection procedures for product from Canadian establishments that wished to participate in the streamlined inspection program. FSIS inspection officials had determined that streamlined inspection procedures could be offered and marking requirements could be eliminated without compromising product wholesomeness. Such procedures were considered to be consistent with the provisions of applicable law and the Free-Trade Agreement, and are discussed in greater detail later in my testimony.

The proposed rule issued by FSIS would amend the Federal meat and poultry products inspection regulations by exempting Canadian meat and poultry products intended to be imported into the United States from requirements contained in Parts 327 and 381 of title 9 of the Code of Federal Regulations, including the requirement that imported product be subject to reinspection by United States import inspectors. FSIS is also proposing to amend Parts 327 and 381 to exempt the Canadian inspection system from various requirements applicable to other foreign countries desiring to obtain and/or maintain their eligibility to export product to the United States and to relieve USDA officials from conducting certain review activities.

Part 312 of FSIS regulations would also be amended by the proposed rule. Under that section, the proposed rule would add a new export stamp to be applied at U.S. establishments to product intended for export to Canada. Part 322 would also be amended by waiving the requirement that an export certificate be issued and accompany product intended for export to Canada and by providing for the use of the new export stamp on product intended for export to Canada.

Lastly, FSIS is proposing to amend Parts 322, 327 and 381 to provide new procedures applicable to U.S. establishments exporting product to Canada and to Canadian establishments exporting product to the United States.

All of these proposed provisions, if made final, would be considered experimental and would be evaluated during and at the end of the experimental period to determine what form of permanent change in procedures may be appropriate. The experimental provisions would not be used for more than 1 year. Once the evaluation is complete, further notice and comment rulemaking would be undertaken to reflect any permanent change in the regulations.

AUTHORITY FOR EXPERIMENT

The Secretary of Agriculture has adequate statutory authority under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) to implement the U.S.-Canada Open Border Agreement. Section 20 of the FMIA, as amended in December 1981, and section 17 of the PPIA, as amended in December 1985 require that all imported meat and poultry products be subject to the inspection, sanitary, quality, species verification, and residue standards applied to products produced in the United States.

The Secretary is required to enforce these requirements through the imposition of random inspection for species verification and residues, and random sampling and testing of internal organs and fat of the carcasses for residues at the point of slaughter by the exporting country, in accordance with methods approved by the Secretary. The Acts do not require the Secretary to conduct these random inspections and testing; the Secretary is only required to enforce the import requirements through these means.

The random sampling and testing of internal organs and fat of carcasses for residues at the point of slaughter must be conducted by the exporting country. The statutes so mandate. However, the Secretary has the discretion to determine whether the exporting or the importing country is to conduct the random inspections for species verification and residues.

In the case of Canada, the Secretary has determined that the inspection system of Canada not only meets the standard of "at least equal to" the inspection system of the United States, but also that the Canadian meat and poultry inspection system is virtually identical to that of the United States. Based on that determination, the Secretary, in his discretion, may delegate the random inspection for species verification and residues to Canadian inspection personnel.

The proposed regulation, therefore, provides for the inspection and reinspection of imported product from Canada by Canadian inspection personnel, and the inspection and reinspection of U.S. product to be exported to Canada by USDA inspection personnel. This inspection procedure, would, in effect, open the border between our two countries with respect to the importation and exportation of meat and poultry products.

The U.S.-Canada Open Border Agreement furthers one of the goals of the U.S.-Canada Free-Trade Agreement found in Article 708(1)(d)—"to utilize each other's personnel for testing and inspection of agricultural, food, beverage, and certain related goods."

The Open Border Agreement is also consistent with Schedule 10 of the Free-Trade Agreement, which specifically relates to meat, poultry and egg inspection. Schedule

10 states that the United States and Canada should work toward making their inspection systems equivalent, and where those systems are equivalent, each country should accept the equivalence of the other.

CURRENT REINSPECTION

The United States will continue to reinspect Canadian products at the border during the rulemaking proceeding. On any given day, inspection in a Canadian meat or poultry plant is the same as in any federally inspected U.S. plant. As was discussed before, Canada does not have a different standard for its domestic products than for products exported to the United States. Like the United States, it has a single standard of inspection for all products.

Since January 1, 1989, all reinspection of Canadian product occurs at border locations in approved import inspection facilities and is performed by trained import specialists. Today, there are 16 approved import inspection facilities at: Buffalo, Gasport, Holley and Champlain, New York; Swanton, Vermont; Caribou, Maine; Detroit, Michigan; Pembina, North Dakota; Sweetgrass, Montana; Eastport, Idaho; and Blaine, Washington.

Following is a description of what happens currently when Canadian meat or poultry products are imported into the United States under the "streamlined" reinspection procedures. Whenever a Canadian shipment is destined for the United States, a representative of the Canadian meat inspection system contacts one of three FSIS Import Field Offices serving the northern border States. These offices are located at Tacoma, Washington; Boston, Massachusetts; and Detroit, Michigan.

FSIS import officials enter the information describing the Canadian consignment into our Automated Import Information System (AIIS) The AIIS is a computer system that drives import reinspections, regardless of the country-of-origin. The computer randomly selects consignments for reinspection. Once selected, a consignment of Canadian product is subject to all of the applicable examinations. Our import inspectors reinspect products using the same statistically based sampling plans that FSIS uses on domestic products.

If the consignment is not selected for reinspection, the product is loaded onto the truck and proceeds to the border and through U.S. Customs controls. Keep in mind that these Canadian products have already been inspected and certified for export by Agriculture Canada. The product then moves to a U.S. establishment for further processing or into distribution channels. Although no formal reinspection is required at the U.S. plant, FSIS in-plant inspectors routinely observe products moving through plants and take appropriate actions to ensure that unsatisfactory product is not used.

If the consignment is selected for reinspection, FSIS informs the Canadian representative of the quantity and specific random numbers of the samples required. The Canadian representative then selects the specific samples, identifies them, and puts them in an easily accessible area of the truck. The truck then proceeds to an official import inspection establishment at the border. An FSIS import inspector then removes the identified samples and proceeds to perform the various inspection procedures that are appropriate for the consignment. These procedures eliminate the need to unload the entire vehicle but still ensure that appropriate reinspection occurs.

There are more than 100 different types of inspections that can be assigned to the variety of products that are imported into the United States. Many of these inspections are unique to specific processed products.

INSPECTION UNDER PROPOSED RULE

Under the proposed rule, some of the current procedures would change. Once U.S. product is ready for export to Canada, the U.S. establishment would be required to telephone or fax information to FSIS in Washington, including the type of product to be shipped, the number of boxes or carcasses to be shipped, the weight of the product, and the Canadian label registration number. An authorization number would be issued to the exporting establishment by FSIS. The exporting establishment would then use this number when stamping the boxes or attaching the number to the carcasses for export. The information noted above and the authorization number would be recorded on a joint form developed for use by both Canada and the United States. This joint form would accompany the product to the border.

When the product reaches the border, the Canadian inspector would check the joint form and would consult the Canadian Import Control System (ICS) to verify issuance of the authorization number. If the authorization number is valid, the product will enter Canadian commerce. If the number appears not to be valid, the

Canadian inspector would contact Agriculture Canada for more information. Agriculture Canada would then consult with FSIS officials. If it is determined that the number is not valid, the shipment would not be permitted to enter Canadian commerce. The joint form and the authorization number will allow any product to be traced should problems later arise.

In short, any federally inspected U.S. establishment could ship product to any place within Canada without being subject to Canadian reinspection procedures and requirements. Neither an export certificate nor a health certificate would be issued. Instead, the boxes or carcasses would be marked with a special, newly developed export stamp containing the authorization number discussed above.

The exportation of Canadian products to the United States would follow the same procedures. For example, once Canadian product is ready for export to the United States, Agriculture Canada officials would be required to contact one of the three FSIS Import Field Offices located in Tacoma, WA; Boston, MA; or Detroit, MI. Agriculture Canada would inform FSIS of the type of product to be shipped, the number of boxes or carcasses to be shipped, the weight of the product, the U.S. label approval number, and the Canadian export inspection number that will be stamped on the boxes or attached to the carcasses. This information would be recorded on the joint form that would accompany the product to the border.

Just as with U.S. exports to Canada, any federally inspected Canadian establishment could ship product to any place within the United States without applying for or having the product be subject to reinspection by U.S. import inspectors. Reinspection of Canadian product and U.S. product is to be done by each respective country before exporting to the other country.

FOOD SAFETY

This 1-year experiment is proposed because USDA is confident of the safety and wholesomeness assurances within the Canadian inspection system. The same is true for the Canadians about the U.S. system.

Food safety is a big issue on both sides of the border. Just as we are hearing food safety concerns about Canadian products, there are many concerns being expressed by Canadians about U.S. products, as well. It is difficult to respond to some of these food safety complaints, especially in the super-heated environment of the increased competition that will result from the Free-Trade Agreement.

We understand the concerns, but the bottom line is that we do not believe food safety is a problem. The Canadian meat and poultry inspection system is virtually identical to the U.S. inspection system and has the same goals—to ensure that meat and poultry products are safe, wholesome, and accurately labeled. We believe Canadian meat and poultry products meet those goals.

SUMMARY

Mr. Chairman, we recognize that implementing an open border policy for meat and poultry will not be easy or noncontroversial. But we believe the open border agreement will facilitate and improve trade of meat and poultry products between the United States and Canada. It broadens the market opportunities for the U.S. meat and poultry industry. U.S. livestock producers, enjoying beef and pork prices at record highs, can use their strong position to make the most of the Free-Trade Agreement.

Some U.S. producers and manufacturers are concerned their Canadian counterparts will "intrude" on the U.S. market. But as with any trade agreement, it's a two-way street. We will see Canadian product move to the United States, just as we will increasingly market and sell U.S. products to Canadian consumers.

This open border agreement truly represents free trade. It is an important step in moving forward with the Free-Trade Agreement. It is shaping our support for free trade into reality.

Mr. Chairman, that concludes my testimony. Again, I appreciate having this opportunity to testify on this very important issue, and I would be happy to answer any questions you or other Senators may have.

PREPARED STATEMENT OF JOHN W. HARMAN, DIRECTOR, FOOD AND AGRICULTURE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE

Mr. Chairman and members of the subcommittee:

We are pleased to be here today to discuss the results of our review of the Food Safety and Inspection Service's (FSIS) streamlined inspection procedures for Canadian meat and our views on the proposed "open border" between the United States and Canada for meat and poultry products. As you know, both the streamlined inspection procedures and the open border proposal were made in response to the 1988 United States-Canada Free-Trade Agreement.

Our testimony is based on a report we issued on July 6 to Representatives Byron Dorgan and Tim Johnson.[1] At their request, we examined five areas related to FSIS inspection procedures for Canadian meat. Our findings are summarized below.

First, we found that the assurance that Canadian meat is wholesome rests primarily on an FSIS determination that Canada's meat inspection system is at least equivalent to the U.S. inspection system. However, we could not independently review the basis for FSIS' determination because it was not adequately documented.

Second, under the streamlined procedures, all Canadian shipments are no longer unloaded at an inspection facility and given a routine visual inspection for general condition. However, selected shipments are still subject to comprehensive inspections for wholesomeness.

Third, rejection rates of Canadian meat were higher in 1989 than in 1988, but the causes and significance of these higher rates are unclear. FSIS cannot account for the differences in the 2 years, or determine whether they are important, in part because it has no criteria for an acceptable rejection rate for Canada.

Fourth, officials from 25 plants that export a substantial amount of meat and poultry to Canada were generally satisfied with the treatment they received under the Canadian inspection system.

And finally, we reported that the open border proposal raises both legal and policy issues that we believe FSIS should address in its decisionmaking on the proposal. For example, a possible legal issue has been raised about whether FSIS has the authority to permanently establish an open border for meat imports or whether the Congress would need to amend the Federal Meat Inspection Act (21 U.S.C. 601 et seq.). From a policy perspective, FSIS needs to ensure that food safety will not be compromised under an open border system by addressing questions raised by our review and others regarding the current program for inspecting meat imported from Canada. For example, the increase in rejection rates for Canadian meat imports experienced under the streamlined inspection procedures and the lack of a well-documented equivalency review of the Canadian inspection system are concerns that need to be addressed.

BACKGROUND

Before providing more detail on our findings, let me briefly give you some background on FSIS' import inspection program and the Free-Trade Agreement. Although the streamlined procedures and the open border apply to both meat and poultry, Canada exports mostly meat to the United States. The Federal Meat Inspection Act requires that meat imports be produced under inspection systems that are at least equal to that of the United States and that the imports are wholesome, unadulterated, properly marked, labeled, and packaged. FSIS is the U.S. Department of Agriculture (USDA) agency responsible for reviewing the inspection systems of eligible exporting countries for equivalency and for inspecting imported meat items at the port of entry to help ensure product integrity.

One goal of the Free-Trade Agreement is to facilitate commerce between the two countries by reducing technical and regulatory trade barriers. The agreement provides that both countries minimize inspection procedures applicable to each other's meat and poultry imports. Generally, it allows each country to make "spot checks" necessary to ensure compliance with the importing country's standards or technical regulations. These spot checks will not exceed those made for domestically produced meat and poultry.

In January 1989, FSIS installed new, streamlined inspection procedures for Canadian meat to ease entry into the United States. In February 1990, following discussions between USDA and Agriculture Canada officials, the U.S. Secretary of Agriculture and Canada's Minister of Agriculture announced their intent to conduct an experiment, of up to 1 year, of an open border for trade in meat and poultry. On June 29, 1990, FSIS published the proposed rule for the open border experiment in the Federal Register. An open border will eliminate port-of-entry inspections by FSIS inspectors.

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[1] *Food Safety: Issues USDA Should Address Before Ending Canadian Meat Inspections* (GAO/RCED-90-176, July 6, 1990).

EQUIVALENCY DETERMINATION

The assurance that Canadian meat is wholesome is primarily based on an FSIS determination that the Canadian meat inspection system meets U.S. standards, that it is at least equivalent to the U.S. inspection system. To determine the Canadian inspection system's equivalency, FSIS officials told us they reviewed Canada's meat inspection laws and regulations; evaluated Canada's ability to control potential hazards, such as residues and disease; conducted onsite reviews of exporting plants; and reviewed data from port-of-entry inspections. This information, the officials said, along with more than 20-years' familiarity with the Canadian inspection system, assure them that the Canadian system is virtually identical to the U.S. system. As a result, they have more confidence in the Canadian inspection system's ability to ensure wholesome meat than they do in other countries'.

However, documentation in FSIS' files was not adequate for us to independently review how FSIS had determined the Canadian system's equivalency or the basis for FSIS' confidence in the Canadian inspection system. For example, although FSIS maintains information in its files on specific aspects of the Canadian meat inspection system, correspondence with Agriculture Canada, and other miscellaneous information, we found no systematic assessment of this information that demonstrates how it supports FSIS' position that the Canadian inspection system is equivalent or virtually identical to the U.S. system.

Because of its high degree of confidence in the Canadian inspection system, FSIS changed the equivalency review process for Canada in two important ways. First, FSIS eliminated its own onsite reviews of Canadian plants. Beginning in 1989, Canadian inspectors have reviewed Canadian exporting plants for FSIS and, under the proposed open border, FSIS and Agriculture Canada plan to end their reviews of each other's exporting plants.

Second, FSIS is not using its standard "systems" approach to assess the Canadian inspection system's ability to control such major hazards as residues and disease. The systems approach uses risk profiles to assess foreign inspection systems' control over five areas—residues, disease, economic fraud (i.e., deliberate adulteration of product), contamination, and processing. FSIS is currently preparing new risk assessments for other countries using updated profiles but has decided to exempt Canada from this process. Instead, FSIS has proposed that, annually, a single team of experts from both countries jointly determine their inspection systems' equivalence. Agriculture Canada is considering FSIS' proposal.

STREAMLINED INSPECTION PROCEDURES

With respect to the streamlined border inspection procedures, several changes have occurred to ease entry of Canadian meat into the United States. Among other things, every shipment of Canadian meat no longer must be unloaded, inspected for general condition and proper labeling, and stamped "U.S. Inspected and Passed." However, Canadian meat is still subject to comprehensive inspections for wholesomeness, although the methodology is now based on 3,000 randomly selected inspections for Canada as a whole. Under the old procedures, comprehensive inspections were tied to the performance history of individual plants. However, in April 1989, FSIS added an intensified inspection program for producing plants that failed the comprehensive inspections.

The two key comprehensive inspections performed on Canadian meat are product examinations and chemical residue tests. In a product examination, the inspector feels, smells, and visually examines exposed product samples to discover defects such as blood clots, bone fragments, extraneous materials, feces, hair, and lesions. For residue tests, the inspector draws samples and sends them to designated laboratories for analysis. The product examination accounts for almost all rejections, by weight, of Canadian meat; few residue tests fail.

The streamlined procedures are controversial because of (1) the advance notice given Canadian plants for shipments that FSIS has selected for inspection and (2) the pulling of samples by Canadian inspectors. These procedures are used so that only trucks carrying Canadian meat selected for inspection have to stop at a U.S. border inspection facility, and when these trucks do stop, they do not have to be completely unloaded. Although FSIS has attempted to strengthen controls and correct problems with its inspection procedures, it continues to allow Canadian inspectors to draw samples for FSIS inspection. This procedure has caused some controversy because FSIS has no control procedure to ensure that samples are pulled in accordance with FSIS instructions; rather, it trusts the Canadian inspector to ensure samples are pulled properly. Further, the FSIS inspectors union has expressed concern about this procedure because it reduces the control its members have over the inspection process. However, if import inspections are eliminated entirely, as now proposed, the use of Canadian inspectors to draw samples for FSIS inspections will no longer be an issue.

REJECTION RATES

Rejection rates of Canadian meat were higher in 1989 under the new streamlined inspection procedures than in 1988, according to FSIS data. In 1989, 3 percent of 3,030 randomly selected lots for Canada as a whole failed product examination; and 8 percent of an additional 1,866 lots were rejected under the intensified inspection program for individual plants failing inspections. In 1988, 1 percent of 13,466 lots failed product examinations.

The causes and significance of the increased 1989 rejection rate are unclear for several reasons. First, the many changes made to import inspection procedures in 1989 make comparisons with prior years difficult. Second, FSIS generally has not used countrywide rejection rates to manage its import inspection program and has no criteria for what constitutes an acceptable rejection rate for Canadian meat. Historically, FSIS has structured its inspection program to focus primarily on ensuring wholesome product from individual plants by intensifying the level of inspection for plants failing inspection. And third, FSIS has not calculated sampling errors for these rejection rates, and thus cannot determine to what extent the increased rates may have resulted from random chance, a decline in product quality, or some other reason.

U.S. EXPORTING PLANTS

Officials from 25 plants that were substantial exporters of meat or poultry products to Canada in 1989 told us that they have received satisfactory treatment under the Canadian import inspection system. The officials were satisfied for three reasons. First, since shipments to Canada were inspected at the destination rather than at the border, delays were minimal. Second, American exporters did not pay for use of inspection facilities in Canada. And finally, these plants experienced minimal rejections of their shipments by Agriculture Canada in 1988 and 1989.

OPEN BORDER RAISES LEGAL AND POLICY ISSUES

Our review identified several legal and policy issues about FSIS' proposal to establish an open border for meat and poultry trade between the United States and Canada.

From a legal perspective, there is a question of whether the open border proposed under the Free-Trade Agreement conflicts with the requirements of U.S. meat inspection laws and whether a legislative change is necessary. FSIS' program officials have raised a possible legal issue about whether FSIS has the authority to permanently establish an open border or whether the Congress needs to amend the Federal Meat Inspection Act. According to USDA's Deputy Assistant General Counsel, the legality of the open border experiment may be an issue that is raised during the public comment period for FSIS' proposed open border rule. The June 29 proposed rule indicates that FSIS believes that adequate legal authority exists for such an experiment.

If, following the rulemaking, FSIS decides to test the open border concept, the key policy issue will be whether FSIS still has adequate import controls to ensure the wholesomeness of Canadian meat. FSIS reviewers no longer review Canadian plants, and an open border will eliminate border reinspections. These are two controls that enabled FSIS to obtain some direct assurance that the Canadian inspection system was functioning in conformance with USDA laws and regulations. Without them, FSIS' equivalency review becomes FSIS' basic management control for ensuring the wholesomeness of Canadian meat. However, as previously mentioned, FSIS is not using its standard systems approach to evaluate the equivalency of the Canadian inspection system and documentation in FSIS' files was not adequate for us to independently review how FSIS had determined the Canadian system's equivalency.

Finally, there is the issue of how FSIS should determine the success of an open border experiment. USDA's March 1990 plan for an open border includes an evaluation plan for determining the extent to which the economic objectives of the Free-Trade Agreement are met during the experiment. The evaluation plan, however, does not discuss how it will assess the effectiveness of an open border in ensuring the safety and wholesomeness of imported meat and poultry. We believe that if FSIS decides to proceed with the open border test after the rulemaking, both the economic and food safety impacts of an open border should be evaluated.

As part of the process for deciding whether to go forward with an open border test, we recommended that the Secretary of Agriculture direct the Administrator, FSIS, to:

—review and document the equivalency of the Canadian inspection system;

—investigate, as part of the equivalency review, the reasons for the high rejection rates in 1989; and

—if the open border test is approved, incorporate into the evaluation plan an assessment of the impact of an open border on food safety.

Mr. Chairman, this ends my prepared statement. I would be glad to respond to any questions.

[The GAO Report to Congressional Requesters, "Food Safety: Issues USDA Should Address Before Ending Canadian Meat Inspections," dated July 6, 1990, follows:]

United States General Accounting Office

GAO

Report to Congressional Requesters

July 1990

FOOD SAFETY

Issues USDA Should Address Before Ending Canadian Meat Inspections

GAO/RCED-90-176

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-239981.1

July 6, 1990

The Honorable Byron L. Dorgan
The Honorable Tim Johnson
House of Representatives

In response to your April 27, 1989, letter and subsequent discussions with your offices, this report examines the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) "streamlined" inspection procedures for Canadian meat.[1] These procedures were introduced in response to the 1988 United States-Canada Free Trade Agreement (Free Trade Agreement). In particular, you asked us to review (1) the process used to determine that the Canadian inspection system meets U.S. standards; (2) how the current border inspection procedures differ from past procedures; (3) how changes in border inspection procedures between 1988 and 1989 affected the rejection rate, and how rejection rates are used to manage the import inspection program; and (4) whether U.S. plants exporting meat to Canada are receiving satisfactory treatment under the Canadian import inspection system.

In February 1990, FSIS and Agriculture Canada proposed conducting a 1-year experiment during which the streamlined inspection procedures would be replaced with an "open border" between the United States and Canada. An open border would eliminate import inspections by FSIS inspectors. As agreed, this report also discusses the legal and policy issues involved in this proposal.

Results in Brief

The assurance that Canadian meat is wholesome is primarily based on an FSIS determination that the Canadian meat inspection system meets U.S. standards, i.e., that it is at least equivalent to the U.S. inspection system. FSIS officials base this determination on their familiarity with the Canadian inspection system and their review of available information. FSIS officials believe that Canada's system is equal, if not virtually identical, to the U.S. system. FSIS is confident that Canada, more so than other countries, can ensure wholesome meat. FSIS has also changed its procedures for determining Canadian equivalency in two principal ways. First, FSIS is not using its standard approach for assessing a foreign inspection system's ability to control such major hazards as residues and disease. Second, beginning in 1989, Canadian inspectors, rather than FSIS reviewers, are conducting on-site reviews of Canadian plants. However, the documentation in FSIS' files was not adequate for us to independently review the basis for FSIS' conclusions about the equivalency of the Canadian inspection system.

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[1] Because Canada exports only a small amount of poultry to the United States, this report refers only to meat, unless otherwise noted.

Under the streamlined border inspection procedures, several changes have occurred to ease entry of Canadian meat into the United States. Among other things, every shipment of Canadian meat no longer must be unloaded, inspected for general condition and proper labeling, and stamped "U.S. Inspected and Passed." Selected Canadian meat shipments are subject to inspections for wholesomeness.

Rejection rates of Canadian meat were higher in 1989 than in 1988, according to FSIS inspection data, but the causes and significance of these higher rates are unclear. In 1989, 3 percent of 3,030 randomly selected lots for Canada as a whole failed product examination; and 8 percent of an additional 1,866 lots were rejected under an intensified inspection program for individual plants failing inspections. In 1988, 1 percent of 13,466 lots failed product examinations. Because FSIS does not calculate sampling errors for rejection rates, it cannot determine to what extent the increased rates may have resulted from random chance, a decline in product quality, or some other reason. Moreover, FSIS has no criteria for an acceptable rejection rate for Canada.

Regarding whether U.S. plants exporting meat to Canada are receiving satisfactory treatment under the Canadian inspection system, our contacts with 25 major U.S. plants indicated they were satisfied.

The open border proposal raises both legal and policy issues. FSIS' program officials have raised a possible legal issue about whether authority exists to permanently establish an open border or whether FSIS needs to ask the Congress to amend the Federal Meat Inspection Act (21 U.S.C. 601 et seq). From a policy perspective, FSIS needs to ensure that food safety will not be compromised under an open border system. Also, we believe the rejection rates experienced under streamlined inspection and the lack of a well documented equivalency review are concerns that FSIS should address in its decision on the proposal.

Background

The Federal Meat Inspection Act requires that meat imports be produced under inspection systems that are at least equal to that of the United States and that the imports are wholesome, unadulterated, properly marked, labeled, and packaged. FSIS does not require a foreign country's controls and practices to be identical to those in the United States, but they must achieve the same results. FSIS is responsible for reviewing the inspection systems of eligible exporting countries for equivalency and for inspecting imported meat items at the port of entry to help ensure product integrity.

One goal of the Free Trade Agreement is to facilitate commerce between the two countries by reducing technical and regulatory trade barriers. The Free Trade Agreement provides that both countries minimize inspection procedures applicable to each other's meat and poultry imports. Generally, it allows each country to make "spot checks" necessary to ensure compliance with the importing country's standards or technical regulations.

In January 1989, FSIS installed new, streamlined inspection procedures for Canadian meat to ease its entry into the United States. During the last quarter of 1989, Agriculture Canada and the Canadian meat industry objected to certain features of the streamlined procedures, citing what they viewed as an excessively high inspection frequency, questionable rejections of Canadian meat, and increased fees charged by private U.S. border inspection facilities. On February 26, 1990, following discussions between USDA and Agriculture Canada officials, the U.S. Secretary of Agriculture and Canada's Minister of Agriculture issued a joint statement announcing, consistent with the spirit of the Free Trade Agreement, their intent to conduct a 1-year experiment of an open border for trade in meat and poultry. An open border will eliminate port-of-entry inspections by FSIS inspectors. If successful, the open border is expected to become permanent. FSIS plans to initiate the open border experiment following a rulemaking procedure.

Determining Equivalency

Since the early 1980s, rather than relying on reviews of individual plants within a country to determine inspection system equivalency,[2] FSIS has been shifting to a "systems" approach, which uses risk profiles to evaluate foreign inspection systems as a whole. The profiles assess an inspection system's control over five areas—residues, disease, economic fraud (i.e., deliberate adulteration of product), contamination, and processing. FSIS first prepared risk profiles in 1983 for eligible exporting countries, including Canada, but by 1987 it found these profiles outdated and no longer useful. Also, FSIS modified and improved upon the risk assessment approach. FSIS is currently preparing new risk assessments for eligible countries using the improved profiles but has decided to exempt Canada from this process.

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[2] FSIS has a permanent staff of veterinarians, called foreign program officers, responsible for conducting plant reviews in exporting countries.

FSIS officials told us that to determine the Canadian inspection system's equivalency to the U.S. system, they reviewed Canada's meat inspection laws and regulations; evaluated Canada's ability to control potential hazards, such as residues and contamination; conducted on-site reviews of exporting plants; and reviewed data from port-of-entry inspections. The officials said that this information, along with more than 20-years' familiarity with the Canadian inspection system, assure them that the Canadian system is virtually identical to the U.S. system. As a result, they have more confidence in the Canadian inspection system's ability to ensure wholesome meat than they do in other countries'.

However, documentation in FSIS' files was not adequate for us to independently review how FSIS had determined the Canadian system's equivalency or the basis for FSIS' confidence in Canada's system.

Because of its high degree of confidence in the Canadian inspection system, FSIS changed the equivalency review process for Canada: It discontinued using its risk profiles and eliminated reviews of Canadian plants conducted by its foreign reviewers. Instead, FSIS has proposed that, annually, a single team of experts from both countries jointly determine their inspection systems' equivalence. Agriculture Canada is considering FSIS' proposal. In addition, Canadian inspectors have reviewed Canadian exporting plants for FSIS since 1989, and under the terms of the February 1990 agreement, FSIS and Agriculture Canada plan to end their reviews of each other's exporting plants.

USDA recognizes the importance of equivalency reviews in guarding against contaminated meat imports. In December 1989, in compliance with the Federal Managers' Financial Integrity Act (31 U.S.C. 3512), USDA reported to the President and the Congress that the lack of completed risk analyses for exporting countries is a material management control weakness that it is correcting.

Streamlined Inspection Procedures

Normal FSIS import inspection procedures require that every shipment of meat and poultry entering the United States be unloaded at a border inspection facility for a routine visual inspection. FSIS often refers to import inspections as reinspections to recognize that imported meat has already been inspected and approved by the exporting country's inspectors. The FSIS inspector examines a shipment for general condition, proper certification, and labeling. Generally, rejections from this type of inspection result from transportation and water damage, labeling deficiencies, and improper certification. In addition, shipments are subject to more comprehensive inspections, using computer-assigned sampling procedures and individual plant performance history, to verify that the product is wholesome and unadulterated. Inspection frequency is increased whenever a shipment fails an inspection. Finally, except in cases where every shipment must be inspected, the shipping plant has no advance notice of whether a particular shipment will be inspected.

The product examination, a key inspection performed on meat imports including Canadian product, accounts for most rejections of Canadian meat. In a product examination, the inspector feels, smells, and visually examines exposed product samples to discover defects such as blood clots, bone fragments, extraneous materials, feces, hair, and lesions.

Under FSIS' streamlined inspection procedures, Canadian meat is no longer given the routine visual inspection or stamped "U.S. Inspected and Passed." However, Canadian meat is still subject to comprehensive inspections for wholesomeness, such as product examinations, although the methodology is now based on 3,000 randomly selected inspections for Canada as a whole rather than on the performance of individual plants. In April 1989, FSIS added an intensified inspection program for producing plants failing the comprehensive inspections. Under this program, 15 consecutive shipments from the responsible plant must stop at a border inspection facility where an FSIS inspector pulls the samples and performs the inspection.

Nevertheless, the streamlined procedures offer Canadian meat exporters a significant advantage over the former procedures. Shipments that have not been assigned one of the more comprehensive inspections can proceed directly to their delivery point.

To determine whether a planned shipment of Canadian meat will be subject to U.S. inspection, a Canadian government inspector calls an FSIS field office and provides product information, which is entered into the FSIS computer system. If the computer system selects a shipment for one of the random inspections, a Canadian inspector draws samples following FSIS instructions and places them in an accessible location in the back of the truck, eliminating the necessity of unloading the entire vehicle. After passing through U.S. Customs, the shipment goes to a privately owned and operated import inspection facility located near the border where the samples are examined by an FSIS inspector.

During 1989, the new procedures experienced several start-up problems, which FSIS has been working to correct. For example, from January through April 1989, 15 truckloads of Canadian meat designated for inspection failed to stop for inspection. As a result, FSIS directed, beginning in April 1989, that plants whose trucks failed to stop for inspection would have to send their next 10 shipments to the border inspection facility regardless of whether the shipment would be inspected. This penalty reduced but did not eliminate the problem. During the last 8 months of 1989, another 22 designated trucks did not stop.

Although FSIS has attempted to strengthen controls and correct problems, it continues to allow Canadian inspectors to draw samples for FSIS inspection. FSIS has no control procedure to ensure that samples are pulled in accordance with FSIS instructions; rather, it trusts the Canadian inspector to ensure samples are pulled properly. The FSIS inspectors union has expressed concern about this procedure because it reduces the control its members have over the inspection process. However, if inspections are eliminated entirely, as now proposed, the use of Canadian inspectors to draw samples for FSIS inspections will be moot.

Rejection Rates

According to FSIS inspection data, the rejection rates of Canadian meat were higher in 1989 than in 1988. In 1989, 90, or 3 percent, of 3,030 randomly selected lots for Canada as a whole failed product examination; and 151, or 8 percent, of an additional 1,866 lots failed inspection under the intensified inspection program. Twenty-one, or almost 8 percent, of 271 randomly selected shipments failed at the Pembina, North Dakota, port of entry, a rate about three times as high as the average rate of six other ports of entry and twice as high as the port of entry with the next highest rate. In 1988, 129, or 1 percent, of 13,466 lots failed product examinations. Data by port of entry could not be developed for 1988.

The causes and significance of the increased 1989 rejection rate and the higher rate at Pembina are unclear for several reasons. First, the many changes made to import inspection procedures in 1989 make comparisons with prior years difficult. Second, FSIS generally has not used countrywide rejection rates to manage its import inspection program and has no criteria for an acceptable rejection rate for Canada. FSIS officials said that the 1989 random, countrywide sampling approach, if followed for several years, may provide a basis for developing better information on rejection rates. Historically, FSIS has structured its inspection program to focus primarily on ensuring wholesome product from individual plants by intensifying the level of inspection for plants failing inspection. And third, FSIS has not calculated sampling errors for these rejection rates, and thus it cannot determine to what extent the increased rates may have resulted from random chance, a decline in product quality, or some other reason.

FSIS has not analyzed the reasons why the rejection rate increased from 1988 to 1989. It has conducted an analysis of 1989 rejection data (see app. III), which shows that low-rated Canadian plants had higher rejection rates than high-rated plants.[3] Because of the proposed open border and limited staff resources, FSIS officials view additional analyses of rejection rates as a low priority.

Others have found the 1989 Canadian rejection rates significant. Beginning in February 1990, the FSIS inspector assigned to the Sweetgrass, Montana, border inspection facility and the president of the U.S.-Canada Border Inspection Association, whose membership includes owners of 12 border inspection facilities, publicly criticized "loose" inspection procedures and expressed concern about "high" rejection rates for Canadian meat. (The Sweetgrass inspector accounted for about 30 percent of all Canadian rejections from product examination failures in 1989.) According to the inspector and the association president, the open border should not be implemented, and FSIS should return to the procedures applied to Canada prior to 1989. They noted that if streamlined procedures were continued, the procedures should be revised so that Canadians do not have advance notice of an assigned inspection. As support for the need for tighter procedures, the inspector provided us with documentation showing that in one 4-day period during May 1990 he rejected five of eight truckloads of fresh pork from one Canadian plant for product examination failures—a total of about 200,000 pounds.

The inspector's and association's concerns have been the subject of stories in a Montana newspaper and several industry publications. The head of FSIS' International Programs office told us that she believes that the inspector cannot generalize from his experience to the overall quality of Canadian product. Although the FSIS official's response is valid, we believe that the inspector's statements will generate confusion and concerns among consumers about the wholesomeness of Canadian meat, and FSIS needs to further evaluate Canadian rejection rates.

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[3] Canada rates its meat-producing plants on a five-point scale in descending order of excellence.

U.S. Plants Satisfied With Canadian Inspection Procedures

Canada has set the level of its import inspections at the same basic rate the United States uses—about one shipment in nine. Canada believes this rate is too high and would prefer to further reduce or eliminate inspections but has decided to follow whatever rate FSIS sets. Agriculture Canada officials told us that their import inspection system for U.S. meat and poultry was not experiencing any problems. Our contacts with 25 major U.S. meat and poultry plants exporting to Canada indicated satisfaction with the Canadian inspection procedures, principally because (1) they do not pay to use Canadian inspection facilities and (2) their meat exports to Canada were accepted, with few exceptions.

Open Border Raises Legal and Policy Issues

Our review identified several legal and policy issues about FSIS' proposal to establish an open border for meat and poultry trade between the United States and Canada.

From a legal perspective, there is a question of whether the open border proposed under the Free Trade Agreement conflicts with the requirements of U.S. meat inspection laws and whether a legislative change is necessary. The United States-Canada Free-Trade Agreement Implementation Act of 1988 (P.L. 100-449) specifies (section 102(a)) that "no provision of the Agreement, nor the application of any such provision to any person or circumstance, which is in conflict with any law of the United States shall have effect." FSIS' program officials have raised a possible legal issue about whether legal authority exists to permanently establish an open border or whether FSIS needs to ask the Congress to amend the Federal Meat Inspection Act. Before the open border agreement, the head of FSIS' International Programs office told us that port-of-entry inspection of Canadian meat imports was required under FSIS' statutes. Subsequently, she told us that a legislative change may be necessary to permanently eliminate import inspection for Canadian product.

On June 29, 1990, FSIS' proposed rule for a 1-year open border experiment was published in the Federal Register. According to USDA's Deputy Assistant General Counsel, the legality of the open border experiment may be an issue that is raised during the public comment period.

If, following the rulemaking, FSIS decides to test the open border concept, the key policy issue will be whether FSIS still has adequate import controls to ensure the wholesomeness of Canadian meat. FSIS reviewers no longer review Canadian plants, and an open border will eliminate border reinspections. These are two controls that enabled FSIS to obtain some direct assurance that the Canadian inspection system was functioning in conformance with USDA laws and regulations. Without them, FSIS' equivalency review becomes FSIS' basic management control for ensuring the wholesomeness of Canadian meat.

Finally, there is the issue of how FSIS should determine the success of an open border experiment. In March 1990, USDA issued a "Joint U.S.-Canada Plan for Implementing the Open Border Experiment in Meat and Poultry Trade," which includes an evaluation plan for determining the extent to which objectives of the Free Trade Agreement are met during the experiment. These objectives are about eliminating trade barriers, facilitating fair competition, and liberalizing conditions for investment. The evaluation plan, however, does not discuss how it will assess the effectiveness of an open border in ensuring the wholesomeness of imported meat and poultry.

Conclusions

Our review identified two areas that raise concerns about whether FSIS' loosening of import controls over Canadian meat will ensure wholesome meat. First, FSIS' determination that the Canadian inspection system is virtually identical to the U.S. system and that FSIS can have more confidence in Canada's ability to ensure wholesome meat than it can for other countries has not been documented to allow an independent, objective review of how FSIS arrived at its determination. Second, the unexplained 1989 rejection rates for Canadian product are cause for concern. Without an adequate explanation, the rates could be interpreted as indicating a decline during 1989 in the effectiveness of the Canadian inspection system. The rates can also be expected to raise concerns in consumers' minds about the wholesomeness of Canadian meat that was not inspected, especially in light of the criticisms from the Sweetgrass inspector and inspection facility owners.

FSIS' proposal for a U.S.-Canadian team to annually review the equivalency of the two inspection systems appears to recognize the need to establish a documented record. FSIS' proposal calls for the preparation of a report that would "serve as a record of the state of equivalence of the two systems." We believe FSIS needs to clearly demonstrate and document that American consumers can rely on the Canadian inspection system to guard against contaminated meat under an open border.

Also, if FSIS decides to proceed with the open border test after the rulemaking, we believe it is important that both the economic and food safety impacts of an open border be evaluated.

Recommendations

As part of the process for deciding whether to go forward with an open border test, we recommend that the Secretary of Agriculture direct the Administrator, FSIS, to

- review and document the equivalency of the Canadian inspection system using the risk assessment systems approach or the proposed team approach;
- investigate, as part of the equivalency review, the reasons for the high rejection rates in 1989; and
- if the open border test is approved, incorporate into the evaluation plan an assessment of the impact of an open border on food safety.

More detailed information on each question is presented in appendixes I, II, and III. Our objectives, scope, and methodology are in appendix IV.

FSIS officials reviewed portions of a draft of this report for technical accuracy, and changes have been made where appropriate. However, requested, we did not obtain official agency comments on this report. As arranged with your offices, we plan to distribute copies of this report to the Secretary of Agriculture and other interested parties.

This work was done under the direction of John W. Harman, Director, Food and Agriculture Issues, who can be reached on (202) 275-5138. Other major contributors to this report are listed in appendix V.

Keith O. Fultz/for

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Abbreviations

AIIS	Automated Import Information System
FMFIA	Federal Managers' Financial Integrity Act
FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
OIG	Office of the Inspector General
USDA	U.S. Department of Agriculture

FSIS' Current Equivalency Review for Canada Is Outdated and Poorly Documented

This appendix discusses the Food Safety and Inspection Service's (FSIS) meat inspection program for exporting countries, including its efforts to develop an effective approach for evaluating the equivalency of foreign inspection systems. The appendix also examines FSIS' reasons for exempting Canada from the standard requirements for exporting countries and assesses the information that is available on the Canadian inspection system.

FSIS' Inspection Program to Ensure Wholesomeness of Imported Meat

The Federal Meat Inspection Act requires that meat imports be produced under inspection systems that are at least equal to that of the United States. The act also provides that, to be imported into the United States, meat items must be wholesome, unadulterated, and properly marked, labeled, and packaged. The U.S. Department of Agriculture's (USDA) FSIS carries out these requirements through an import control program centering on (1) the review of foreign inspection systems, supplemented by on-site reviews of inspection activities in foreign plants,[1] and (2) port-of-entry inspection.

The review of a foreign country's inspection system is to be completed using the risk analysis systems approach. This approach examines the exporting countries' entire system of maintaining security over a product as it moves from point of production to the loading dock for export. FSIS considers the eligible foreign countries' inspection system the primary control for ensuring that imported meat and poultry products meet U.S. standards.[2] Port-of-entry inspections are intended as a check on the effectiveness of foreign inspection systems in ensuring that wholesome, accurately labeled products are imported that meet U.S. standards.

FSIS Efforts to Develop a Systems Approach

Since the mid-1960s, FSIS has sought to develop an import inspection program that ensures protection "equal to" that provided by its domestic inspection program. In 1963, FSIS began an on-site review process of the operations in individual plants certified to export to the United States. In 1966, FSIS formalized this procedure and established a permanent staff of veterinarians, called foreign program officers, responsible for conducting plant reviews. Over the next decade, FSIS believed that this review procedure served the needs of the public adequately for the amount of resources that were invested. However, during those years the volume and the product variety of foreign exports changed significantly, and FSIS realized that the acceptability of individual plants greatly depended on the controls built into each country's inspection system.

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[1] FSIS has a staff of foreign program officers, who are licensed veterinarians with experience in domestic inspection; they evaluate foreign inspection systems and conduct periodic reviews of establishments certified to export to the United States to determine if U.S. requirements are being met.

[2] Examples of U.S. inspection standards required of other countries include (1) the assignment of competent, qualified inspectors and (2) national inspection officials with sufficient authority and responsibility to enforce meat inspection laws and regulations and to certify or refuse to certify product intended for export.

In November 1979, a USDA task force report recommended comprehensive changes to reorient the resources of the imported meat and poultry inspection program to ensure that the inspection process focuses on examining the most critical areas of a meat inspection system. The task force criticized the agency's reliance on individual plant reviews as a means of assessing the adequacy of foreign inspection systems and proposed that a systematic method be developed to evaluate each country's regulatory control system. According to the task force, by concentrating on individual establishments rather than entire inspection systems, the program was focusing resources on proving the compliance of particular products from particular plants on a periodic basis rather than on ensuring the effectiveness of foreign country inspection programs over the long run.

To improve the equivalency review process and shift its focus from plant reviews, the task force report identified various risk areas that needed to be analyzed as part of a systematic review of a country's meat inspection system. A risk area analysis is the process of (1) assessing a hazard in terms of its severity, probability, and the extent of its impact and (2) measuring each country's ability to control the hazard. A risk area analysis is not intended as a one-time look at a country but as an ongoing and dynamic process that reflects changes occurring in the country.

In response to the 1979 task force recommendations, FSIS began developing the methodology and necessary tools to conduct risk area analyses. For example, a profile instrument was developed for each risk area that could affect meat acceptability. In 1983, risk area profile assessments were conducted for all meat exporting countries' inspection systems for the risk areas identified in the 1979 task force report. These assessments evaluated how a foreign inspection system deals with certain risk areas: residues, diseases, additives, gross contamination, microscopic contamination, economic fraud, and compliance.

Program officials, however, found this initial effort did not adequately assess the risks associated with a country's meat inspection program and began to develop a revised risk profile format. By 1987, the risk area profiles identified in the 1983 systems approach review were modified to reflect a more accurate systems approach review of a foreign country's inspection system. It included residues, disease, contamination, processing, and economic fraud/compliance. FSIS believes it now has created an appropriate way to implement a systems approach, and it is preparing new risk area profiles for eligible countries, except Canada. The reasons for exempting Canada are discussed in subsequent sections of this appendix.

Reinspection at Port of Entry

The second aspect of import inspection is inspection of product at the port of entry. FSIS refers to port-of-entry inspections as reinspections because all the imported product has already been examined and approved by the exporting countries' own inspection systems. FSIS inspectors are required to examine each lot of a product for general condition, proper certification, and labeling. In addition to this limited visual inspection, individual shipments are subject to further, more thorough inspections, based on computer-assisted sampling procedures, to verify that the product is wholesome and unadulterated.[3]

The import reinspection program acts as a spot-check of the country's inspection system and gathers data to evaluate the continuing performance of the foreign inspection system. However, FSIS considers the eligible foreign countries' inspection system, not port-of-entry reinspection, the primary control for ensuring that imported meat products meet U.S. standards.

USDA Cites Inadequate Systems Approach as a Material Management Control Weakness

In 1983, 1987, and 1989, GAO and USDA Office of the Inspector General (OIG) reports recommended that USDA place greater emphasis on completing the development and implementation of systems approach reviews, instead of individual plant reviews, for the countries eligible to export meat to the United States. USDA has cited the lack of an effective systems review approach as a material management control weakness and is taking action to update systems reviews for all countries, except Canada, by September 1991.

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[3] Port-of-entry inspection procedures are discussed in detail in app. II.

GAO Reports

In two reports, we found that FSIS was not completing its systems approach review expeditiously. In 1983,[4] we concluded that FSIS was making slow progress in ensuring that foreign countries' regulations were equal to U.S. regulations, especially for the systematic approach the 1979 task force recommended. In 1987,[5] we concluded that the risk profiles, which form the basis for the systems approach, should be updated to better ensure the safety of imported meat. Specifically, the report found FSIS' acquisition of data to support its foreign country evaluations was piecemeal, and important information, such as the risk profiles, was not current.

OIG Reports

In its 1987 report on FSIS' imported meat process,[6] USDA's OIG said that FSIS needs to more effectively utilize the systems approach to evaluate a country's eligibility to export meat and/or poultry products to the United States. The OIG concluded that FSIS did not have reasonable assurance that systemic problems in foreign inspection systems were detected and corrected. Therefore, an increased risk exists that products not meeting U.S. standards are exported to the United States. The OIG also recommended that FSIS revise and evaluate the most current information concerning eligible countries' meat inspection programs to determine whether the foreign systems have remained equal to that of the United States. In a 1989 follow-up,[7] the OIG emphasized the importance of implementing the systems approach recommendations made in 1987 and the need to centrally maintain documentation supporting the residue certification of foreign countries.

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[4] Improved Management of Import Meat Inspection Program Needed (GAO/RCED-83-81, June 1983).

[5] Imported Meat and Livestock: Chemical Residue Detection and the Issue of Labeling (GAO/RCED-87-142, Sept. 1987).

[6] Food Safety and Inspection Service: Audit of the Imported Meat Process (USDA/OIG, Audit Report No. 38002-2-Hy, Jan. 1987).

[7] FSIS Follow-Up Audit of the Imported Meat Process (USDA/OIG, Audit Report No. 38002-4-Hy, Mar. 1989).

Inadequate Systems Reviews Cited as Material Management Control Weakness

The Federal Managers' Financial Integrity Act (FMFIA) (31 U.S.C. 3512) requires agencies to assess and report annually to the President and the Congress on the adequacy of the internal management controls in their programs.

In its fiscal year 1988 and 1989 FMFIA reports, USDA described how FSIS' evaluation systems are not designed to detect and correct systemic problems in the inspection programs of countries exporting to the United States. The USDA reports cited the following FSIS material weaknesses and planned action with a scheduled completion date of September 1991:

- Material Weakness: Evaluation systems are not designed to detect and correct systemic problems in the inspection programs of countries exporting to the United States. Planned action: Fully implement conversion of the foreign inspection review program to a systems approach instead of the plant-by-plant approach.
- Material Weakness: New written guidance is needed for evaluating the inspection programs of foreign countries. Planned action: Develop and issue written guidance to foreign program officers as the systems review approach is implemented.

Status of Systems Approach Reviews

FSIS plans to complete support materials and risk area profiles for all countries, except Canada, at the rate of one per year through 1991. To date, two risk area profiles, contamination and residues, have been completed and another risk profile, processing, is scheduled to be completed this year.

Systems Approach and Plant Evaluations Will Not Be Done for Canada

Since January 1989, FSIS has made two major changes to the equivalency review process for the Canadian system. First, the systems approach risk area analyses will not be done for Canada. Instead, FSIS has proposed an annual equivalency review to be conducted by a single team of experts from both countries, with a single report prepared. FSIS believes this approach to equivalency is more appropriate for Canada, given its close relationship with the United States.

Second, FSIS' foreign program officers are no longer conducting on-site evaluations of Canadian plants, nor are Agriculture Canada inspectors conducting similar evaluations of U.S. plants. Before 1989, FSIS had a foreign program officer assigned to examine all aspects of the Canadian inspection system, including its plants, on a regular basis. Similarly, Canadian reviewers routinely traveled to the United States and looked at establishments exporting to Canada. However, in 1989 FSIS began a new procedure: It now accepts on-site evaluations conducted by Agriculture Canada's internal review group and Agriculture Canada accepts FSIS' evaluations of domestic plants conducted for Agriculture Canada.[a] (Each country's inspection service has an internal audit group that evaluates the work of the inspection service. Inspectors from these internal audit groups now conduct the on-site plant evaluations.)

FSIS supports these changes because it believes that the Canadian meat inspection system is more like the U.S. system than is that of any other country. This equivalency is based on the close similarity between the goals, objectives, and other features of the two countries' inspection systems. Although FSIS recognizes that other countries have inspection systems "at least equal to" the U.S. system, FSIS believes the Canadian system is virtually identical to the U.S. system. (FSIS' standard of acceptability is equivalence with the U.S. inspection system; this means that controls and practices do not have to be identical to those in the United States if they achieve the same results.) As a result, FSIS has more confidence in the Canadian inspection system's ability to ensure wholesome meat than it does in other countries'. According to the head of FSIS' International Programs, the enactment of the Free Trade Agreement between the United States and Canada served as a mechanism to reduce the regulatory and bureaucratic burdens that each country imposes on each other and helped hasten the changes that had already been considered.

FSIS officials base their high degree of confidence in the Canadian inspection system on about 20 years of a close working relationship with Canadian inspection officials and a detailed familiarity with the Canadian inspection system. On the basis of this experience, and the expertise and judgment of FSIS' professional staff, FSIS believes that the Canadian inspection system is virtually identical to the U.S. system. However, we did not find documentation in FSIS' files supporting this belief.

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[a] Under the recent Feb. 26, 1990, U.S.-Canada agreement, both countries plan to eliminate altogether on-site reviews of each other's plants if the proposed 1-year test of the open border proves successful. Success will be determined by a joint U.S.-Canadian team that will evaluate how well the test meets five objectives of the Free Trade Agreement: (1) elimination of trade barriers, (2) facilitation of fair competition, (3) liberalization of investment, (4) establishment of effective administrative procedures, and (5) establishment of further cooperation to expand and enhance the benefits of the agreement.

FSIS' Current Equivalency Review for Canada Is Outdated and Poorly Documented

Our evaluation, like our prior findings on all exporting countries, found that the available information on Canada's equivalency is outdated and fragmented. This information is not assembled in a document that systematically assesses the Canadian inspection system. Although FSIS officials said that they have a management process that periodically consolidates, analyzes, and summarizes information to determine the equivalency of the Canadian inspection system, our review of agency files found that this process was not documented.

The original equivalency review conducted for Canada in about 1970 evaluated the laws, policies, and administration of Canada's inspection system. However, FSIS did not prepare summary reports or management documents of this evaluation. An initial systems approach using the risk area profiles was completed in 1983 but has not been updated to reflect the revised and improved systems approach's risk areas. Although FSIS maintains more current information in its files on specific aspects of the Canadian meat inspection system, daily correspondence with Agriculture Canada concerning specific problem areas, and other miscellaneous information, we found no systematic assessment of this information that demonstrates how it supports FSIS' position that the Canadian inspection system is equivalent to the U.S. system. Also, documentation was not available in FSIS' files to allow an independent, objective review of how FSIS' arrived at its determination that the Canadian inspection system is virtually identical to the U.S. system and that FSIS can have more confidence in Canada's ability to ensure wholesome meat than it can in other countries'.

Appendix II

U.S. And Canadian Streamlined Inspection Procedures for Imported Meat

This appendix discusses the streamlined inspection procedures FSIS instituted in 1989 in response to the Free Trade Agreement.

FSIS Inspection Procedures for Canadian Meat

FSIS' 1989 streamlined inspection procedures for Canadian meat differ in several respects from previous procedures. FSIS, however, did not change its residue testing program, which checks for drugs and other chemical residues that may occur in meat products.

Under normal FSIS import inspection procedures, which Canada followed prior to the Free Trade Agreement and all other eligible foreign countries still follow, meat and poultry entering the United States must be unloaded at inspection facilities for a routine visual inspection.[1] The FSIS inspector examines a shipment for general condition, proper certification, and labeling. Product defects found in this inspection are generally related to transportation and water damage, inadequate labeling, and improper certification.

In addition, certain computer-selected shipments are subject to further, more comprehensive inspections to verify that the product is wholesome and unadulterated. The computer selects these shipments taking previous plant performance and the nature of the product into account. Inspection frequency is increased whenever a shipment fails an inspection. Also, except in cases where every shipment must be inspected, the shipping plant has no advance notice of the computer's inspection assignments.

The two key inspections performed on Canadian meat are product examinations and chemical residue tests. The product examination is an "organoleptic" type of inspection in which an inspector feels, smells, and visually examines exposed product samples to discover defects such as blood clots, bone fragments, extraneous materials, feces, hair, and pathologic lesions. For residue tests, the inspector draws samples and sends them to designated laboratories for analysis. Almost all rejections (by weight) of Canadian product result from product examination failures; few residue tests fail.

If meat passes these inspections, it (or the shipping containers) is stamped "U.S. Inspected and Passed," the product is reloaded, and the truck proceeds to its destination. Meat and poultry failing import inspection are refused entry; marked "U.S. Refused Entry;" and destroyed, converted to nonhuman food use, or returned to the originating country.

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[1] FSIS often refers to import inspections as reinspections to recognize that imported meat has already been inspected and approved by the exporting country's inspection system.

In 1988, Canadian exporting plants or their importers could elect to have inspection performed by FSIS either at inspection facilities near the port of entry or at the shipment's delivery point. Canadian plants would make their choice on the basis of such factors as cost and convenience.

Changes in 1989

In January 1989, under general provisions of the Free Trade Agreement to minimize inspections and remove barriers to trade, FSIS changed its inspection procedures for Canadian meat to ease entry into the United States. These changes, which FSIS called streamlined procedures, eliminated some inspections and reduced others. But the streamlined procedures involve more than just reducing the level of inspection. In certain areas FSIS has fundamentally changed its approach for inspecting Canadian product.

Canadian meat is no longer given the routine, visual inspection or stamped "U.S. Inspected and Passed." However, Canadian product is still subject to the more thorough types of inspection, such as product examinations, although the basic sampling methodology is now based on 3,000 randomly selected lots for Canada as a whole rather than on the past performance of individual plants. In 1989, all 3,000 lots selected were given at least a product examination. However, FSIS made no changes in its residue-testing approach for Canada because it believed it had a clear legislative mandate for a strong-residue-testing program for imported meat and poultry. In fact, the sampling rate for residue tests of Canadian product, as set forth in FSIS' annual residue test plan, increased from 3,900 sample units in 1988 to 4,700 units in 1989 because of a relatively high number of Canadian violations in 1988. (More than one residue sample may be taken from a randomly selected lot.)

Also, beginning in January 1989, Canadian shippers no longer had the option of choosing the delivery point as the place where the FSIS inspection would be performed. If an inspection was required, it had to be performed at an inspection facility near the port of entry. This policy change did not result from the Free Trade Agreement but from a 1986 agency decision to improve control prior to inspection by requiring that imported product be inspected as soon as it enters the United States.

To determine whether a planned shipment of Canadian meat will be subject to a product examination, a residue test, or other types of inspection under the streamlined inspection procedures, the Canadian inspector calls an FSIS field office and provides product information, which is entered into the FSIS computer system. If the computer system selects the shipment for detailed inspection, the samples at participating Canadian plants are (1) drawn by Canadian inspectors according to FSIS instructions and (2) placed in an accessible location in the back of the truck.[2] After passing through U.S. Customs, the shipment must go to a privately owned and operated import inspection facility located near the border where the samples are examined by an FSIS inspector. Samples may be drawn up to 3 working days prior to FSIS inspection. If a shipment is not selected for any of the detailed inspections, the shipment can proceed directly to its destination, stopping at the border generally for only a paperwork check by U.S. Customs.

First Year Start-Up Problems

During its first year, the streamlined inspection procedures experienced several start-up problems. These problems appear to have been caused by (1) FSIS' decision to implement the procedures shortly after the effective date of the Free Trade Agreement and (2) limited testing and analysis of the new procedures.

Although the Congress approved the agreement in September 1988, the Canadian government did not give its approval until November 1988. The agreement was a controversial issue in Canada, and its approval by Parliament was uncertain. The agreement became effective on January 1, 1989. FSIS conducted no documented analysis or assessment of the impact of its proposed procedures nor did it evaluate alternatives. Although a pilot test of some elements of the proposed procedures was conducted during October 1988, no written report or analysis was prepared on test results.

Start-up problems with streamlined inspection included the following:

- From January through April 1989, 15 truckloads of Canadian meat designated for inspection "bypassed" FSIS border inspection facilities and failed to stop for inspection. FSIS attributed the bypasses to the Canadian plants' unfamiliarity with the new procedures. To deal with this situation, FSIS directed in April 1989 that plants found bypassing inspection would have to send their next 10 shipments to the U.S. border inspection facility. In spite of this penalty, however, bypassing continued, with FSIS reporting 22 bypasses from May through December 1989.

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[2] Import inspection procedures call for two different types of sampling. One type selects individual shipments or lots for inspection. If a shipment is selected for inspection, the other sampling type determines how portions of the overall shipment are selected for examination. For example, if a 40,000-pound shipment is selected for inspection, procedures may call for the inspector to draw 30 12-pound samples at random from the overall shipment. On the basis of the inspector's findings on these 30 samples, the entire 40,000-pound shipment is accepted or rejected.

- In April 1989, partly in response to an increased rejection rate of Canadian product, FSIS established an intensified inspection program for individual plants failing inspections. Under this program, if a plant fails a product examination, the next 15 shipments from that plant must stop at a border inspection facility where the samples are pulled by FSIS inspectors who perform the product examinations. For the 8-month period in 1989 during which the intensified inspection program was in effect, FSIS' performed 1,866 intensified inspections.
- The import inspection computer system, quickly reprogrammed to implement the new procedures for Canada, exhibited certain data problems. First, the computer system could not distinguish between inspections assigned on the basis of the 3,000-countrywide sampling plan and those assigned under the intensified inspection program. Consequently, FSIS could not determine the overall Canadian rejection rate. In early 1990, FSIS staff had reviewed 1989 inspection files to identify rejections resulting from the countrywide samples. Second, the system was double-counting some inspection failures and understating the weight of others. FSIS appears to have corrected these problems in 1990.

No FSIS Control Over Samples Drawn by Canadian Inspectors

FSIS has no control mechanism to ensure that its sampling procedures are properly performed at Canadian plants, other than its trust in the integrity of Canadian inspectors. In our view, the primary issue raised by these revised sampling procedures is not whether Canadian inspectors can be relied on to follow them, but whether the procedures themselves and the lack of FSIS oversight instill consumer confidence. In this respect, our work raised several concerns.

First, the Canadian inspector who is selecting the samples is part of the Canadian inspection system that FSIS import inspections are evaluating. To have the person being evaluated pull his or her own sample creates the appearance that the sampling process lacks independence and objectivity. Second, Canadian inspectors and officials told us that if a Canadian inspector pulls a sample that is clearly contaminated, the inspector would substitute another sample because he or she could not allow contaminated product to leave the plant. Substituting for a sample that would be rejected lowers the overall rejection rate and clearly destroys the integrity of the sampling process. And third, in a visit to 1 of the 10 largest Canadian exporting plants, we found that pulling samples properly in accordance with FSIS instructions can be a time-consuming and difficult process within the busy operational environment of a typical large Canadian processing plant. (The manager of this plant decided to have the FSIS inspector draw the samples even though this may cause some delay at the U.S. border inspection facility.) While there is no evidence that Canadian inspectors are not following FSIS instructions when drawing samples, the apparent difficulty of pulling samples at Canadian processing plants and the possibility that new samples could be substituted for contaminated samples are conditions that are not conducive to an inspection program in which consumers can have confidence. However, if inspections are eliminated entirely, as now proposed, the use of Canadian inspectors to draw samples for FSIS inspection will no longer be an issue.

In contrast to FSIS procedures, Agriculture Canada representatives meet U.S. trucks at the border, where they determine whether a shipment will be inspected. Consequently, a U.S. plant does not know until its truck reaches the Canadian border whether a shipment will be inspected. If an inspection is assigned, the samples are selected by the Canadian inspector when the shipment arrives at its destination.

U.S. Customs Does Not View Contraband as a Problem

We were also asked whether the current streamlined procedures protect against the shipment of contraband.

U.S. Customs has primary responsibility for preventing contraband from entering this country. Customs officials told us that although FSIS' streamlined procedures provided the opportunity for smuggling contraband into the United States, they did not believe this was a problem. According to Customs officials at the two ports of entry we visited, Customs inspections for contraband are usually generated by tips and informal sources of information, rather than random testing of trucks entering the United States. With respect to drugs, they noted that Canada considers the United States a source for drugs and other contraband, not the reverse. In addition, Customs is now installing a random inspection process for the Canadian border. This system will identify high-risk shipments that will be subject to an intensive examination.

U.S. Plants Satisfied With Canadian Inspection Procedures for U.S. Meat and Poultry

Agriculture Canada has reciprocated for the U.S. streamlined procedures and reduced the level of its import inspection to the same rate as FSIS—about one shipment in nine. Agriculture Canada would prefer to reduce the level of inspection to a much lower rate but has decided to follow whatever rate FSIS sets. However, Canada's import inspection system differs from the U.S. system in ways that create several advantages for U.S. plants. For example, Canada conducts import inspections not at ports of entry but at the destination point where the truck will be unloaded, whether or not the shipment is inspected. Also, the U.S. plant does not have to pay a fee for use of Canadian inspection facilities. Agriculture Canada officials told us that their import inspection system for U.S. product is not experiencing any significant problems.

American plants exporting meat and poultry to Canada told us that they have received satisfactory treatment under the Canadian import inspection system. We contacted officials from 25 plants that were substantial exporters of meat or poultry products to Canada in 1989. Overall, these officials were satisfied with the Canadian inspection procedures and had not experienced any serious problems. Their responses indicated several reasons for their overall satisfaction. Since shipments to Canada were inspected at the destination rather than at the border, enroute delays were minimal. Also, American exporters did not pay for inspection services performed in Canada. (The fees charged by U.S. inspection facilities are an irritant to some Canadian plants.)

And finally, these plants experienced minimal rejections of their shipments by Agriculture Canada in 1988 and 1989. Although the plants contacted typically shipped 1 or 2 trucks to Canada each week, 18 plants reported they had had no rejections in 1989. The other plants reported only a few rejections. The pattern was similar in 1988.

Some plant officials did report problems with the paperwork required. They did not always know what Canada's requirements were or believed that the Canadian inspectors were unnecessarily meticulous about the preparation of the paperwork. Plant officials also reported that Agriculture Canada officials were very helpful in working out problems.

Appendix III

Reasons for Higher Rejection Rates in 1989 Are Unclear

This appendix discusses FSIS' information on Canadian rejection rates and examines the possible explanations for differences between the 1988 and 1989 rates. It also explains how FSIS uses rejection rates in managing its import inspection program.

Rejection Data Stored in Computer System Are Generally Reliable

Rejection data on imported product are maintained in FSIS' Automated Import Information System (AIIS), a computerized system that centralizes inspection and shipping information from all U.S. ports. Information stored in the system includes the amount of products offered from each foreign country and establishment, inspection results, and the amount refused entry.

Our analysis of rejection data focused on product examinations performed and failed in each year. Except for residue testing, product examination is the basic type of inspection performed on Canadian product and the primary reason for rejecting Canadian product. We did not look at residue tests because relatively few Canadian shipments fail these tests; FSIS reported 26 residue violations in 1988 out of 6,916 Canadian samples analyzed and only 7 violations in 1989 out of 3,173 samples analyzed.

Because our analysis of computer-processed rejection data was important for achieving our objectives, we tested the reliability of these data for 1989 by comparing the computer-processed data with paper source documents, including field office Refused Entry Logs, health certificates, and inspection results forms. Generally, inspection and rejection data were reliable, except for data on the weight of rejected shipments. We found rejected weight data to be inaccurate because of inadequate software changes made to the computer system to reflect changes made to Canadian inspection procedures during 1989. FSIS made additional software changes to correct this problem in January 1990.

Rejection Rates for Canadian Product Show Increase in 1989

According to FSIS inspection data, rejection rates for Canadian meat increased in 1989. As shown in table III.1, the rejection rate was about 1 percent in 1988 and about 5 percent in 1989. In addition, as shown in table III.2, the 1989 rejection rate of 5 percent resulted from a 3-percent rejection rate for product examinations performed under the random-based inspection approach and an 8-percent rate under the intensified inspection approach for plants failing inspections. These rejection rates should be reviewed with certain data limitations in mind. First, FSIS officials emphasized that rejection rates reported under the countrywide inspection program are not comparable to rejection rates reported under the intensified inspection program. Second, sampling errors and confidence intervals have not been calculated for these rejection rates. Consequently, FSIS cannot determine to what extent the increased 1989 rates were actually the result of random chance due to statistical variability. (Sampling error for rejection rates is discussed later in this appendix.) And third, since the size of inspected lots can vary from a few thousand to over 40,000 pounds, a more meaningful comparison of rejection rates would also include data on the weight of rejected lots, adjusted to reflect the different lot sizes. However, reliable and consistent data on the weight of rejected lots were not available to make comparisons between 1988 and 1989.

Table III.1: Comparison of Canadian Meat and Poultry Inspection Data for 1988 and 1989

Data categories	1988	1989
Weight of product offered for entry into U.S. (in millions of pounds)	680	693
Total lots offered for entry into U.S.[a]	61,254	26,629
Lots inspected for a product examination	13,466	4,896
Ratio of lots assigned a product examination to total lots	1:4.5	1:5.4
Total lots failing a product examination	129	241
Percent of lots inspected failing a product examination	1	5

[a] A lot is made up of products produced by one plant that are similarly packaged and processed. A truckload can include single or multiple lots. In 1989 FSIS broadened its definition of a "lot" by grouping similar products together into single, "generic" lots, thereby eliminating inspections on many small lots of similar products.

Source: Data obtained from FSIS' Automated Import Information System.

Table III.2: Analysis of Canadian Lots Failing Product Examinations in 1989

Data categories	Number inspected	Number rejected	Percent rejected
Lots assigned a product examination on the basis of countrywide random selection	3,030	90	3
Lots from specific plants inspected because of prior product examination failures	1,866	151	8

Source: Data obtained from FSIS' Automated Import Information System.

Twenty-one, or almost 8 percent of 271 randomly selected shipments failed at the Pembina, North Dakota, port of entry, a rate about three times as high as the average rate of six other ports of entry and twice as high as the port of entry with the next highest rate, according to our analysis of AIIS data of the seven border ports of entry.[1] Agriculture Canada officials have expressed concern about the high failure rate at

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[1] The private import inspection facilities are generally located within a few miles of the ports of entry along the U.S.-Canadian border.

Pembina and reported to FSIS that reinspection of refused shipments revealed no deficiencies.

FSIS cannot explain why rejection rates increased in 1989 or whether the rates were within acceptable ranges. FSIS has not analyzed the reasons why the rejection rate increased from 1988 to 1989. According to a FSIS' analysis of the 3,030 random inspections performed in 1989, rejections varied by the quality of the producing plant and by product category. In an April 1990 paper, Reinspection of Canadian Product Presented for Import Into the United States During 1989, FSIS reported that ratings of Canadian plants were related to the rejection of lots: Higher rated plants had lower rejection rates. Agriculture Canada rates its plants on a five-point scale in descending order of excellence —AAA, AA, A, B, C. FSIS' analysis found that the A-and B-rated plants had rejection rates (3.9 and 3.7 percent) about twice those of the AAA- and AA-rated plants (1.7 and 2.2 percent). C plants had relatively few product examinations performed on their product; none of which failed. The FSIS paper also found that product categories, such as boneless manufacturing meat and headmeat, had significantly higher rejection rates than other product categories, such as wholesale meat cuts. For example, 3 of 18 lots of headmeat were rejected—a 16.7-percent rejection rate.

However, the FSIS paper did not comment on the meaning of any of the reported rates for the import inspection program. For example, the paper did not comment on whether the higher rates for the lower rated plants and for some product categories were acceptable or not.

FSIS Uses Rejection Data to Monitor Performance of Individual Plants

FSIS officials have not focused attention on the higher rejection rates in 1989 because their management approach is directed towards ensuring acceptable performance from individual foreign plants, not towards evaluating changes in a country's overall rejection rate.

Generally, FSIS does not use a country's overall rejection rates on inspection failures to manage its import inspection program. It does not have criteria or a standard rate for what is an acceptable level of rejection for Canada, nor does it have threshold or target rates that trigger action when rejections rise to a given level. FSIS does not have standard or target rejection rates for imported product because it does not maintain data on rejection rates for domestic meat and poultry.[2] Rather, FSIS uses rejection data primarily to monitor and react to the performance of individual plants. Where it finds a problem, FSIS responds by intensifying the level of inspection for subsequent shipments from that plant. FSIS officials believe that this approach will force the plant to either improve or stop exporting to the United States.

Since import inspections have been generally directed at monitoring individual plant performance, FSIS maintains that overall rejection rates have little meaning for a country as a whole. FSIS officials pointed out that the 3,000-countrywide sampling plan applied to Canada in 1989 offers FSIS its first opportunity to collect statistically sound data on a country's overall rejection rate. However, the officials also noted that they would need several years' data using this new sampling approach before they could make any meaningful analyses of changes in rejection rates from year to year. If the countrywide sampling approach proves useful, FSIS said it would consider applying it to other countries. However, with the recent U.S.-Canada agreement to conduct an experiment eliminating all import inspections, the issue of FSIS' sampling approach for Canadian product may be moot.

Reasons for Higher Rejection Rates Are Unclear

It is not clear why the rejection rate increased in 1989 and Pembina had a high rejection rate. It was difficult to analyze 1989 rejection rates for several reasons. First, overall rejection rates for 1989 and prior years cannot be directly compared because many changes were made to Canadian import inspection procedures in 1989. For example, in 1989, the 3,030 inspections performed were randomly assigned by the AIIS for Canada as a whole without regard to individual plant performance. In contrast, the 13,466 inspections in 1988 were assigned on the basis of individual plant performance, with plants failing inspections receiving more frequent inspections.

Second, even with the different procedures, rejection rates for 1989 could be compared with prior years if FSIS calculated sampling errors for rejection rates.[3] Sampling errors could help FSIS determine whether increased rejection rates are due to a random chance or whether product quality has actually declined. For example, if the sampling error was plus or minus 1 percent, an increase in the rejection rate from 2 percent to 3 percent could be explained by random chance. However, FSIS has not calculated confidence intervals to reflect the degree of sampling error in rejection rates. FSIS explained that the performance-based sampling approach used in past years was directed at ensuring quality product from individual plants, not at determining a country's overall rejection rate. FSIS believes that going back to past years to calculate confidence intervals now would be complicated and not worth the effort required. However, FSIS' statistician said that calculating the sampling error for the 3,000 countrywide, random inspections taken in 1989 was much more practical. He estimated that the sampling error for the 3,000 inspections would be less than plus or minus 1 percent.

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[2] Until FSIS installed its nationwide, computerized Performance-Based Inspection System in 1989, it did not have the capability to collect national data on inspection results. FSIS officials said that they are now beginning to study ways to use the data from this system to improve both the domestic and import inspection programs.

Third, as noted previously, FSIS has no criteria or standards for what it considers an acceptable rejection rate. Although the rejection rate of U.S. product inspected domestically could be a reasonable standard for assessing the product of other countries, FSIS does not collect such data. Without any standard for what is an acceptable quality level for imported product, FSIS does not know whether the Canadian countrywide and Pembina rejection rates reported during 1989 are within acceptable ranges.

For these reasons, neither we nor FSIS could explain the increased rejection rate in 1989 and the high rate at Pembina with certainty. However, our analysis and discussions with FSIS officials suggest several possible explanations. For example, FSIS inspectors are not uniformly performing product examinations. In other words, some inspectors may reject more product because they are more conscientious, thorough, or experienced than other inspectors. Data for 1989 show that the rejection rate of FSIS import inspectors performing at least 25 random product examinations varied from 0 percent to 9 percent, with 9 percent the rejection rate for the inspector who performed most of the product examinations at Pembina. FSIS contends, however, on the basis of a special study, that its import inspectors are performing inspections uniformly. FSIS suggests instead that some Canadian plants are shipping more product through Pembina in 1989 that cannot pass a product examination.

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[3] An inspection or quality control system is generally based on statistical sampling because testing all lots of a product would be inefficient and costly. According to standard statistical sampling theory, an import inspection system should be able to estimate the rejection rate along with the sampling error associated with that rejection rate.

Related explanations include differences in product quality among plants and differences in product quality in the same plant over time. An additional explanation offered by FSIS, as mentioned earlier, is that comparisons between 1988 and 1989 are difficult, if not impossible, given the many changes to inspection procedures made in 1989.

Appendix IV

Objectives, Scope, and Methodology

Our objective was to provide answers to a series of questions pertaining to four areas of U.S. and Canadian import meat inspection: equivalency determination, inspection procedures, rejection rates, and treatment of American plants exporting to Canada. Specifically, we addressed the following questions:

- Equivalency determination. What process has FSIS followed to determine that Canada's inspection system is equal to the U.S. inspection system?
- Inspection procedures. How do the current streamlined inspection procedures for Canada differ from procedures in 1988? What controls does FSIS have to ensure that the current sampling procedures are properly performed by Canadian inspectors? Do the current procedures protect against the shipment of contraband or contaminated meat?
- Rejection rates. How does the rejection rate under the system implemented on January 5, 1989, compare with the rejection rate under the previous system? Do the rejection rates reported in 1989 vary significantly by port of entry? If there are significant differences in rejection rates, is there any apparent explanation? How does FSIS compute rejection rates for imported product? How does FSIS use rejection rates to manage its import inspection program?
- Treatment of American plants. Has Canada instituted a similar streamlined inspection system for American meat being exported to Canada? If so, is this system experiencing any problems? Are American plants exporting to Canada basically satisfied that they are receiving satisfactory treatment under the Canadian import inspection system?

In addition, we were asked to comment on, on the basis of our field work, what we believe are the major issues that FSIS should address in its rulemaking proceeding to eliminate import inspection of Canadian meat.

To learn about FSIS' process for determining the equivalency of the Canadian inspection system, we reviewed FSIS' files for Canada; prior reports by GAO and USDA's Office of Inspector General, which included evaluations of the equivalency review process; and discussed the equivalency process with officials from FSIS' International Programs office.

To evaluate FSIS' 1989 streamlined inspection procedures for Canadian meat and compare them with 1988 procedures, we reviewed regulations, instructions, and procedures governing FSIS' meat inspection activities for 1988 and 1989. To better understand how the 1989 import inspection procedures for Canadian meat differed from 1988 and from procedures followed for all other countries, we made field visits to two FSIS field offices in Detroit, Michigan, and Tacoma, Washington, and U.S. Customs ports of entry and four border inspection facilities at Detroit and Blaine, Washington. We also observed several inspections performed by FSIS import inspectors on meat from Canada and two other countries.

With respect to rejection rates, we obtained data from the Automated Import Information System, a computerized system that centralizes inspection and rejection data from U.S. ports. Because our analysis of computer-processed rejection data was important to accomplishing our review objectives, we tested the reliability of these data for 1989 by comparing the computer-processed data with paper source documents, including field office Refused Entry Logs, health certificates, and inspection results forms. Our tests found that generally inspection and rejection data were reliable, except for data on the weight of rejected shipments. We found rejected weight data to be inaccurate because of inadequate software changes made to the computer system to reflect changes made to Canadian inspection procedures during 1989. FSIS has begun making additional software changes to correct this problem. The implementation of the changes began in January 1990.

To determine whether Canada has instituted similar streamlined inspection procedures for American meat, we reviewed Agriculture Canada's import inspection procedures and discussed them with Agriculture Canada and FSIS meat inspection officials. We also contacted 25 major U.S. meat and poultry exporters to Canada to obtain comments on their experience with Canadian inspection procedures in 1989.

We also discussed various aspects of FSIS' import inspection program with FSIS' import inspectors, Canadian inspectors, border inspection facility owners, U.S. Customs headquarters and field office officials and inspectors, the American Meat Institute, the Canadian Meat Council, USDA's Office of Inspector General and Office of the General Counsel, and USDA's Assistant Secretary for Marketing and Inspection Services.

We conducted our work from July 1989 to March 1990, primarily at FSIS headquarters in Washington, D.C. Our review was performed in accordance with generally accepted government auditing standards. Our examination of the adequacy of internal controls and compliance with applicable laws and regulations was performed to the extent necessary to answer the questions asked by the congressional requesters. Our examination of internal controls included a review of USDA's 1988 and 1989 reports to the Congress on USDA's evaluation of its management controls and financial management systems, as required by the Federal Managers' Financial Integrity Act.

We discussed the factual information in this report with FSIS officials during the course of our work and have incorporated their views where appropriate. However, as your offices requested, we did not obtain official agency comments on this report.

Major Contributors to This Report

Resources, Community, and Economic Development Division, Washington, D.C.

Edward M. Zadjura, Assistant Director
Lou Schuster, Assignment Manager
Max L. Aguilar, Staff Evaluator
Mitchell B. Karpman, Statistician
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Chicago Regional Office

Dale A. Wolden, Regional Management Representative
Paul I. Wilson, Evaluator-in-Charge

PREPARED STATEMENT OF MICHAEL J. COPPS, SENIOR VICE PRESIDENT, LEGISLATIVE AFFAIRS, AMERICAN MEAT INSTITUTE (AMI), WASHINGTON, DC

Thank you, Mr. Chairman. I am Michael J. Copps, senior vice president of legislative affairs for the American Meat Institute (AMI). Accompanying me this morning is John Gould, AMI manager of inspection services. The American Meat Institute appreciates the opportunity to present our views on the joint U.S./Canada agreement to implement a 1-year open border experiment in meat and poultry trade.

AMI is the national trade association representing all segments of the meat packing and processing industry. Our members produce over 90 percent of the Nation's meat products. Headquartered in Arlington, VA, the Institute conducts economic and scientific research, sponsors a variety of educational programs, and provides public and government relations services on behalf of the meat industry.

Both the U.S. and Canadian livestock and meat industries maintain a highly competitive, productive trading relationship. Canada is one of our largest export markets for U.S.-produced meat products. Last year, the U.S. exported to Canada beef, pork, lamb and poultry worth $360 million. At the same time, the United States imported from Canada $564 million worth of red meat and poultry products. Total weekly cross-border trade in red meat and poultry approached $18 million.

The balance of meat trade favors Canada on pork and the United States on beef, lamb and poultry. Even though we are a net importer of Canadian meat products, the close proximity and market similarities make Canada one of our most valued trading partners. Any development that has the potential to enhance trade between our two countries, such as the Free-Trade Agreement, is of utmost importance to the meat industry.

On February 26 of this year, USDA and Agriculture Canada announced their intent to test the feasibility of an open border with respect to trade in meat and poultry products. The 1-year experiment would exempt each country's meat and poultry products from reinspection at the border. If successful, the experiment is expected to form the basis for permanent changes in inspection procedures that would facilitate trade between the United States and Canada.

The open border project would implement provisions to harmonize standards for meat and poultry inspection, which were contained in the United States-Canada Free-Trade Agreement. This action complements both countries' stated goal of international harmonization of sanitary and phytosanitary standards in the Uruguay round of the General Agreement on Tariffs and Trade.

The open border test will be characterized by:

- full reciprocal acceptance of each country's inspection procedures,
- continuation of existing label approval procedures that reflect each country's specific requirements, and
- implementation of special export procedures to ease trade restrictions.

Following the February announcement by both governments to test an open border concept, USDA published proposed rules on June 29 to implement the basic provisions of the agreement as previously outlined.

The AMI supports the joint U.S./Canada open border meat and poultry inspection experiment to foster more free and open trade. In my view, our future economic viability depends on expanding world trade, not only for the meat industry, but for all of American agriculture.

AMI believes that the open border experiment deserves a fair chance to work. Our U.S. inspection system is more similar to Canada's meat inspection system than to that of any nation in the world. Each country's inspection program is staffed by professional veterinarians and meat inspection specialists who are fully capable of performing a neutral, third-party inspection on behalf of all consumers.

It is important to understand clearly the scope of the open border proposal. All meat and poultry products will continue to be inspected by the respective government agencies. Periodic reviews of each country's inspection systems will continue to assure that all meat and poultry products are wholesome, unadulterated, properly marked, labeled and packaged.

Importers will be required to obtain advanced approval of labels for meat and poultry containers from FSIS' Standards and Labeling Division. All Animal and Plant Health Inspection Service requirements to control animal diseases, all Food and Drug Administration's requirements to approve animal drugs, and all U.S. Customs requirements concerning duties, tariffs or other trade-related matters will remain virtually unchanged.

This means rigorous inspection will continue under existing health and safety standards. U.S. laws and regulations will apply to Canadian products entering U.S. commerce. Only *reinspection* at the border of previously inspected products will be discontinued. The envisioned changes do not affect basic consumer protection because the open border test does not change the way Agriculture Canada or the USDA inspects products at the plant.

We believe the open border experiment reflects the commitments and the cooperation embodied in the United States-Canada Free-Trade Agreement. This is a necessary and logical step to eliminate trade barriers between our respective countries. Nevertheless, we must be ever-vigilant that such agreements maintain the highest standards for safety and wholesomeness in the meat and poultry products our citizens consume.

Incidents will arise where product is determined not to meet the importing country's regulatory requirements. Similarly, respective product standards may occasionally vary according to the special needs of the importing country. The use of certain animal drugs and random sampling for illegal residues are often cited as examples.

It is important to remember that not all U.S. and Canadian production, processing and inspection requirements are identical. Nevertheless, each country's system is designed to produce safe and wholesome products.

Occasionally, problems can occur within any jurisdiction, but they should not be viewed as an indictment of the entire system. As problems are identified, AMI believes that they must be quickly and effectively addressed.

To that end, AMI and our Canadian counterpart, the Canadian Meat Council, have proposed a bilateral panel to monitor meat and poultry inspection during the experiment with open border trade. The panel would be government-appointed and comprised of industry, consumer and government representatives. It would be commissioned to evaluate the 1-year trial, identify problems, and recommend how a permanent bilateral inspection program could be implemented.

The panel would oversee the test and properly evaluate the results to assure that both countries maintain the highest standards for safety and wholesomeness of meat and poultry imports. Additionally, the panel would provide a necessary mechanism to address complaints and provide a repository for feedback on how the proposed system is working to protect public health. We envision the bilateral panel working hand-in-hand with the existing governmental Meat, Poultry and Egg Inspection Working Group that is commissioned to implement the broader precepts embodied in the Free-Trade Agreement.

Our objective is simple: free and fair trade of safe and wholesome meat and poultry products between the United States and Canada. If we can make free trade work between the United States and Canada, free trade with other countries becomes a more realistic possibility. Maintaining public confidence in our respective inspection systems is a necessary prerequisite to achieving that goal. We believe the panel we have proposed will help us in that regard.

Mr. Chairman, we urge this committee to consider our views carefully during this important juncture in implementing provisions of the United States-Canada Free-Trade Agreement. Thank you for the opportunity to appear before this distinguished committee.

[The prepared statement of Kenneth Schiltz and attached exhibits A-G follow:]

TESTIMONY OF KENNETH SCHILTZ,
VICE PRESIDENT OF SCHILTZ FOODS, INC., BEFORE
THE SENATE SUBCOMMITTEE ON AGRICULTURAL AFFAIRS
ON JULY 12, 1990

Mr. Chairman, members of the Senate Agricultural Subcommittee on Research and General Legislation, at the invitation of Senator Thomas Daschle, Chairman of this subcommittee, I have been invited to testify concerning the implementation of the United States and Canada "Open Border" Agreement with respect to poultry inspection. By way of introduction, my name is Kenneth Schiltz, and I am Vice President of Schiltz Foods, Inc., a South Dakota corporation, whose principal place of business is located in Sisseton, South Dakota.

Schiltz Foods, Inc., is engaged in the processing of geese, and goose products, as well as the processing of Kosher Duck. A sister corporation, Schiltz Goose Farm, Inc., of which I am also the Vice President, is engaged in the raising of geese and have a farm, comprising 280 acres of land, with breeding facilities and grow-out facilities located thereon.

Schiltz Foods, Inc., and Schiltz Goose Farm, Inc., was founded by my father, Marlin Schiltz. In 1944, Marlin was given five (5) Toulouse goose eggs by his wife's sister, and from those five (5) eggs he hatched out two (2) goslings that averaged out twelve (12) pounds of body weight and sold for twelve (12) cents per pound. From that humble beginning, my father went on to develop the largest integrated goose production facility in the United States. Further, my father developed the only North American bred goose which is registered with the Department of Agriculture in Maryland and known as the Schiltz Line 306.

Schiltz Foods, Inc., and Schiltz Goose Farm, Inc., are both family corporations. Myself, my brothers, Richard and James, and my father, Marlin, are the officers and shareholders of these corporations. As stated earlier, our production facility is located on 280 acres of land west of Sisseton, South Dakota. On this farm, we have 5,000 laying hens and 1,200 ganders. From this flock, of various pedigrees, are produced between 90,000 to 120,000 goslings. This breeder flock has been developed over the last 36 years with copious records being kept to develop a goose that meets certain specifications.

Marlin's goal has been to develop a large meat producing bird with a white skin, large breast and white feathers. Through market research over the years, it was determined that the American consumer did not care for a dark skinned, small goose, but wanted a large breasted, white skinned goose. This goal has been achieved and now the Schiltz Line 306 is the most sought after goose in the United States and Europe for breeding purposes.

Schiltz Goose Farm, Inc., employs nine (9) employees on a year around basis. This does not count James, Marlin, Richard and myself, Again, the farm produces the goslings that ultimately end up to be the finished goose. The farm does not have the capacity to raise all of these goslings to maturity. Therefore, every year, the farm sells approximately 70,000 goslings to farmers in South Dakota, North Dakota, Minnesota, Iowa, and Montana.

On the farm itself, we raise approximately 32,000 goslings to maturity. These goslings are raised both for processing and for replacement breeder stock. Between the farmers production and our farm, there will be approximately 82,000 ready for processing in the fall. This equals out to approximately eighty-two percent (82%) of our total production.

The other 18,000 birds will be furnished by other farmers who have our breeding stock on hand. These other farmers are located in the State of Montana.

Schiltz Foods, Inc., processes all of the geese produced by Schiltz Farm, Inc., and the other farmers. The physical plant is located in the City of Sisseton, and is a USDA approved facility. During its processing season, this plant will process between 100,000 to 107,000 geese.

During its processing season, Schiltz Foods, Inc., will employ between 160 and 175 people. Some of these employees have been categorized as "hard core" unemployed, in that most are members of the Sisseton-Wahpeton Sioux Tribe, which has its headquarters in Roberts County, South Dakota. The annual payroll is approximately $ 660,000.00, per year. To some, this is the only income that their family would generate during a year.

During the last six (6) years, we have seen an erosion in our markets because of the influx of Canadian processed geese. This has been due to a number of factors, but the most significant of these was a loss by the Canadians of their overseas market, the exchange rate between the U. S. and Canadian currency, and the fact that

Canadians have a loosening of their processing regulations concerning the grading of their birds while the regulations on U. S. processed geese are ever tightening in regards to grading.

Each processor strives to achieve an "A" grading upon their Bird because the American consumer has been taught to buy only that product that has an "A" rating. The USDA has placed strict regulations upon what type of bird can receive an "A" grade. When a bird has received the USDA "A" shield the consumer can be assured that he is receiving the best. There are more production costs in producing a grade "A" bird than an ungraded bird or a grade "B" bird. The problem is that the Canadian "A" bird is not of the same quality as the USDA grade "A" bird.

An example being, in the U. S. if a wing is trimmed on a bird, then the other wing must be trimmed. The USDA states that this must be done to retain a USDA Grade A label. In Canada, in order to receive a Canadian "A" shield, if a wing is trimmed, the other wing does not have to be trimmed.

Further, I would refer you to Exhibit "A", attached, pictures one and two. On June 30, 1990, one of our officers went to a Supermarket in Fargo, North Dakota, and purchased 3 frozen Canadian Grade "A" geese from Hornbacher's Village West Supermarket. The sales slip showing that purchase is attached on Exhibit "B".

As you can see from these pictures, one wing has been trimmed at the first joint and the other wing has not been trimmed in any way. This seems like a small item, but what it results in is a loss by the U. S. processor of approximately $10,600.00 a year. Now this is not an isolated incident because in November of 1989, we went out and purchased 120 Canadian Grade A processed geese. We bought them from an independent distributor in Chicago. We brought those geese to our plant in Sisseton and had a USDA regional grader, Stan F. Rausch, grade them, utilizing USDA standards. Of these 120 birds, 50 of them did not meet USDA Grade A requirements, see the attached Exhibit "C", being a USDA grading certificate.

Also noted, but not on the grading certificate, there were no livers present with the giblets. Now, the significance of the fact that there was no liver with the giblets is that in the United States, if you want a Grade "A" rating, the liver must be included in the giblets. It is obvious that in Canada, in order to get a Canadian "A" rating, you do not have to have the liver included in the giblets.

Further, I would refer you to Exhibit "D", pictures one and two. Again, these are pictures taken of the three geese purchased on June 30, 1990, in Hornbacher's in Fargo. As you can see on picture one, the label says that this is a Canada "A" grade goose, with giblets included. As you can see in picture two, the only giblets included are the two pieces of the gizzard and the heart. The liver was absent.

Again, this seems like an insignificant item, but it is not. Goose liver is used to make liver pate'. A prime goose liver used to be worth $6.00 per pound. The reason being that liver was hard to come by without buying the whole bird. Now, the Canadians can still market an "A" bird without the liver and then sell the liver separately. If a U. S. processor could omit the liver and still market the bird as a Grade "A" bird, he could realize approximately another $70,000.00 in income per year. But he cannot, so the U. S. producer is once again out about $70,000.00 per year.

After the experiment in November of 1989, the USDA was notified and as you can see by the letter of Jo Ann R. Smith, copy is attached and marked Exhibit "E", the USDA did further checks which resulted in 994 cartons of frozen geese, or 3976 geese, being returned to Canada for not meeting USDA grade "A" specifications, and 521 cartons, or 2084 geese, having the Canadian grade "A" shield removed.

Further, in Canada, the processor does not have to pay for a Government Grader, the Government furnishes that person. In the United States, the processor must reimburse the Government for a USDA Grader. The cost to the processor is approximately $7,600.00 a year.

The USDA is very strict about enforcing the regulation requiring that pinfeathers be removed from the bird. If a U. S. processor wants a Grade "A" rating, then his bird must be free of pinfeathers, diminutive feathers and hair, which are visible to the grader. Canada, on the other hand, only requires that the bird be free of pinfeathers.

The cost to the U. S. processor in meeting this requirement is approximately $51,200.00 per year. The cost to a Canadian processor is much less, in that, of those 120 birds that we purchased and graded, most had pinfeathers on them. Again, see Exhibit "F" which is attached, showing the amount of pinfeathers on the birds purchased from Fargo.

Further, find attached a letter from Mr. Don Swanberg, a person who has been a distributor of poultry products in the northeastern United States for 40 years, marked Exhibit "G", wherein he states that the Canadian goose product is not of the same quality as the U. S. grade "A" goose product. That even though the Canadian goose product was not of the same quality, it still outsold the American product because it carried a Canadian "A" shield and was priced lower.

Mr. Chairman, the reason we are here today is not to oppose free trade with Canada, as we believe that free trade is vital to our world economy. What we want is not only free trade, but fair trade. There is a difference. The Canadians are being allowed to ship a product to the United States under a Canadian "A" shield when in fact their product should be a USDA grade "B" product or Parts Missing.

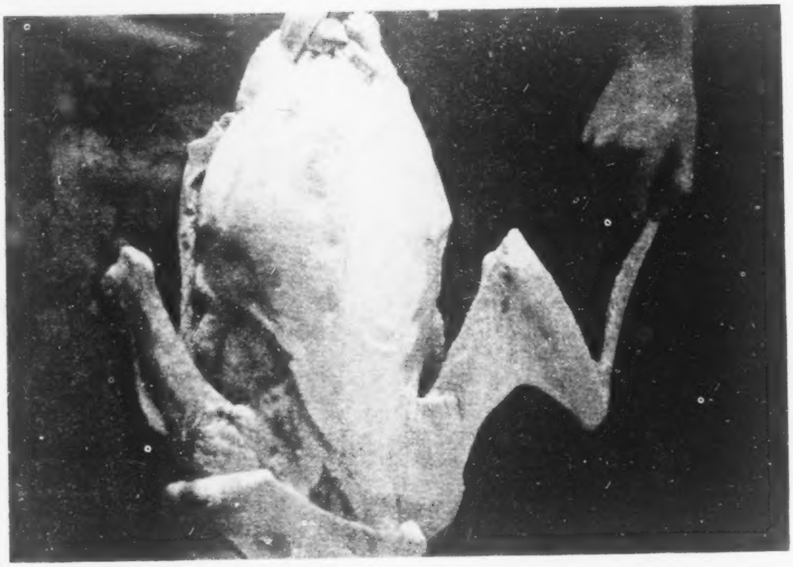
That difference being in the amount of regulation being imposed upon the parties. We believe that it is imperative any system adopted for inspection and grading of poultry products entering the United States from Canada, cannot be "nearly" identical. It has to be totally identical. The "nearly" identical system we have now costs us approximately $140,000.00 per year, not counting the twenty percent (20%) difference in exchange rates and the lost market share, because of these factors. It is our belief that if the Canadians are not held to the strict system we are held to, this figure could triple. At that point, it is no longer feasible to process geese in the United States. This means that a forty-six (46) year old family business will cease to exist and that 160 to 170 people will lose their jobs.

What we want, Mr. Chairman, is not decreased inspection of products coming into the U. S., but increased inspection and grading. People who wish to import their products into this country must be held to the same standards as our own citizens. The USDA has worked hard to insure that the American consumer receives only the best product available. They are very strict about enforcing these regulations in plants in the United States. To now open the border to allow a product to enter the United States and compete with a higher quality product that costs more to produce but yet labeling that imported product as a higher quality product is perpetrating a fraud upon the American consumer and denying equal protection to the citizens of this Nation.

THANK YOU MR. CHAIRMAN.

EXHIBIT "A"

Picture One



Picture Two

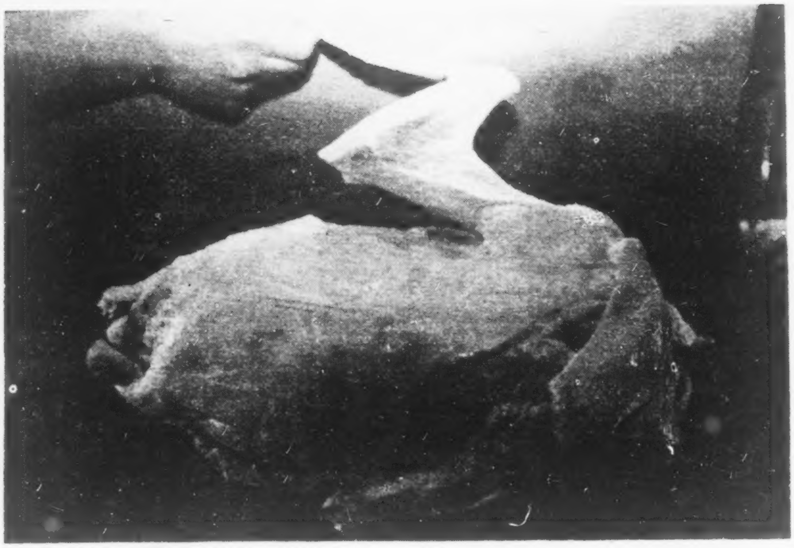
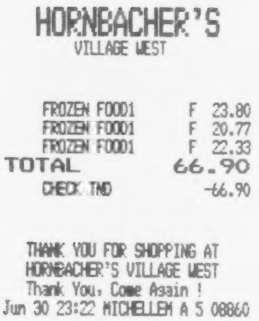


EXHIBIT "B"

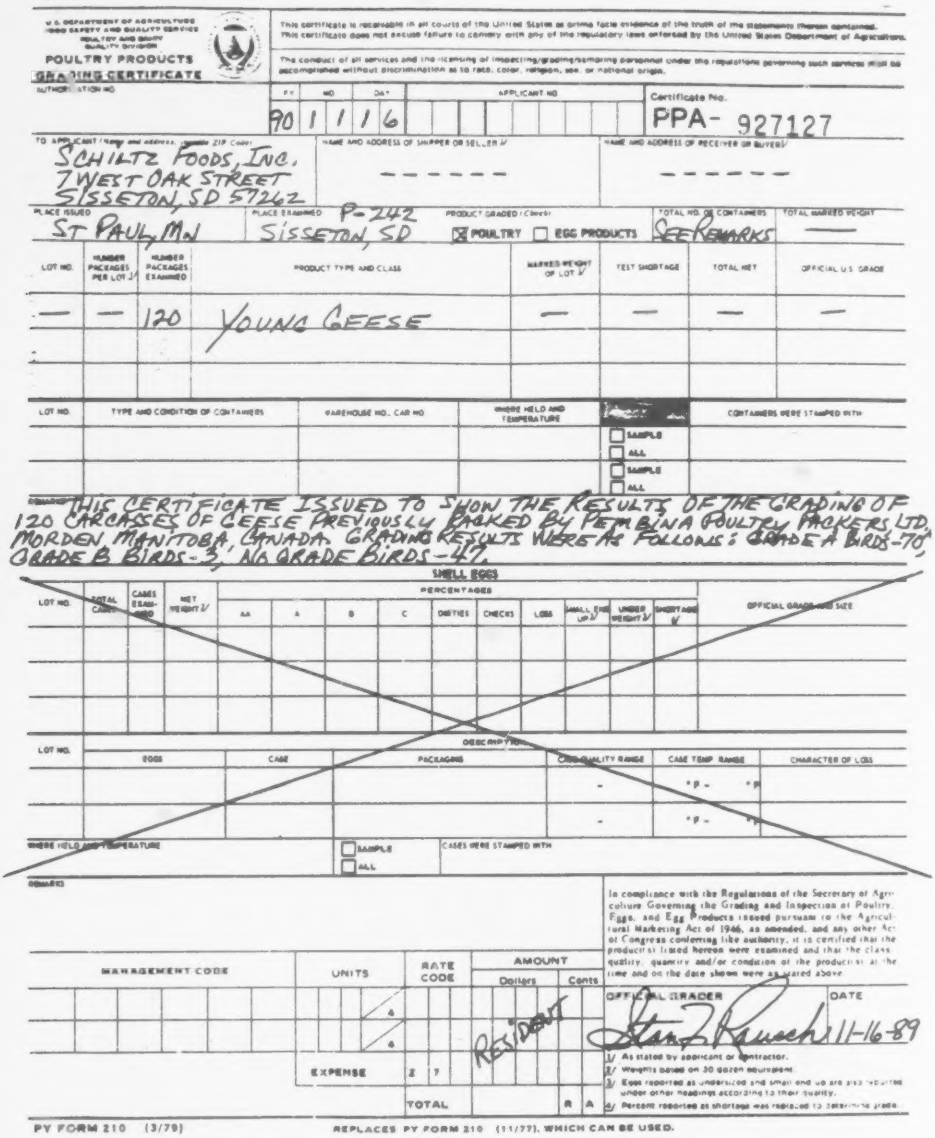


HORNBACHER'S
VILLAGE WEST

FROZEN FOOD1	F	23.80
FROZEN FOOD1	F	20.77
FROZEN FOOD1	F	22.33
TOTAL		66.90
CHECK TND		-66.90

THANK YOU FOR SHOPPING AT
HORNBACHER'S VILLAGE WEST
Thank You, Come Again !
Jun 30 23:22 MICHELLEM A 5 08860

EXHIBIT "C"



U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND QUALITY SERVICE
POULTRY AND DAIRY
QUALITY DIVISION

POULTRY PRODUCTS GRADING CERTIFICATE

This certificate is receivable in all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the United States Department of Agriculture.

The conduct of all services and the licensing of inspecting/grading/sampling personnel under the regulations governing such services shall be accomplished without discrimination as to race, color, religion, sex, or national origin.

AUTHORIZATION NO.

FY	MO		DAY		APPLICANT NO.	Certificate No.
90	1	1	1	6		PPA- 927127

TO APPLICANT (Name and address, include ZIP Code)
SCHILTZ FOODS, INC.
7 WEST OAK STREET
SISSETON, SD 57262

NAME AND ADDRESS OF SHIPPER OR SELLER 1/ ------

NAME AND ADDRESS OF RECEIVER OR BUYER 1/ ------

PLACE ISSUED: ST PAUL, MN

PLACE EXAMINED: P-242 SISSETON, SD

PRODUCT GRADED (Check): ☒ POULTRY ☐ EGG PRODUCTS

TOTAL NO. OF CONTAINERS: SEE REMARKS

TOTAL MARKED WEIGHT: —

LOT NO.	NUMBER PACKAGES PER LOT 1/	NUMBER PACKAGES EXAMINED	PRODUCT TYPE AND CLASS	MARKED WEIGHT OF LOT 1/	TEST SHORTAGE	TOTAL NET	OFFICIAL U.S. GRADE
—	—	120	YOUNG GEESE	—	—	—	—

LOT NO.	TYPE AND CONDITION OF CONTAINERS	WAREHOUSE NO., CAR NO.	WHERE HELD AND TEMPERATURE		CONTAINERS WERE STAMPED WITH
				☐ SAMPLE ☐ ALL	
				☐ SAMPLE ☐ ALL	

REMARKS THIS CERTIFICATE ISSUED TO SHOW THE RESULTS OF THE GRADING OF 120 CARCASSES OF GEESE PREVIOUSLY PACKED BY PEMBINA POULTRY PACKERS LTD, MORDEN, MANITOBA, CANADA. GRADING RESULTS WERE AS FOLLOWS: GRADE A BIRDS-70, GRADE B BIRDS-3, NO GRADE BIRDS-47.

SHELL EGGS

LOT NO.	TOTAL CASES	CASES EXAMINED	NET WEIGHT 2/	PERCENTAGES AA	A	B	C	DIRTIES	CHECKS	LOSS	SMALL END UP 3/	UNDER WEIGHT 3/	SHORTAGE 4/	OFFICIAL GRADE AND SIZE

LOT NO.	DESCRIPTION EGGS	CASE	PACKAGING	CASE QUALITY RANGE	CASE TEMP. RANGE	CHARACTER OF LOSS
				-	°F - °F	
				-	°F - °F	

WHERE HELD AND TEMPERATURE ☐ SAMPLE ☐ ALL CASES WERE STAMPED WITH

REMARKS

MANAGEMENT CODE	UNITS	RATE CODE	AMOUNT Dollars	Cents
	4		RESIDENT	
	4			
	EXPENSE	2 7		
		TOTAL		R A

In compliance with the Regulations of the Secretary of Agriculture Governing the Grading and Inspection of Poultry, Eggs, and Egg Products issued pursuant to the Agricultural Marketing Act of 1946, as amended, and any other Act of Congress conferring like authority, it is certified that the product(s) listed hereon were examined and that the class, quality, quantity and/or condition of the product(s) at the time and on the date shown were as stated above.

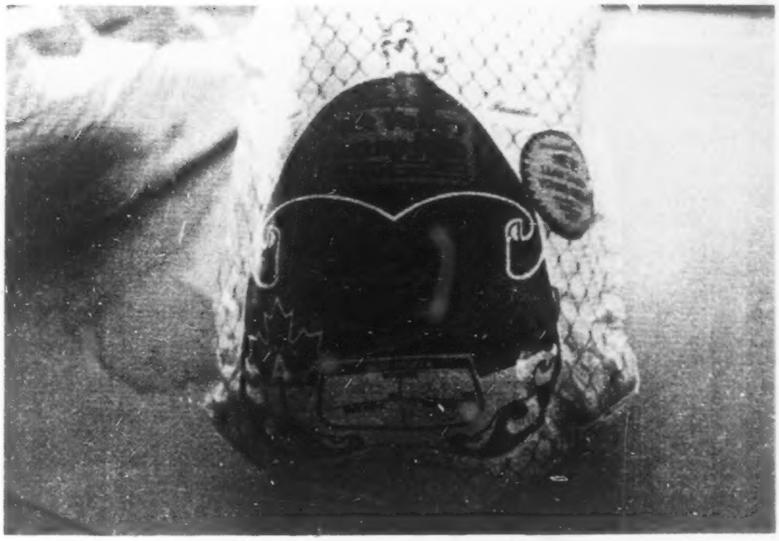
OFFICIAL GRADER Stan Rausch DATE 11-16-89

1/ As stated by applicant or contractor.
2/ Weights based on 30 dozen equivalent.
3/ Eggs reported as undersized and small end up are also reported under other headings according to their quality.
4/ Percent reported as shortage was replaced to determine grade.

PY FORM 210 (3/79) REPLACES PY FORM 210 (11/77), WHICH CAN BE USED.

EXHIBIT "D"

Picture One



Picture Two

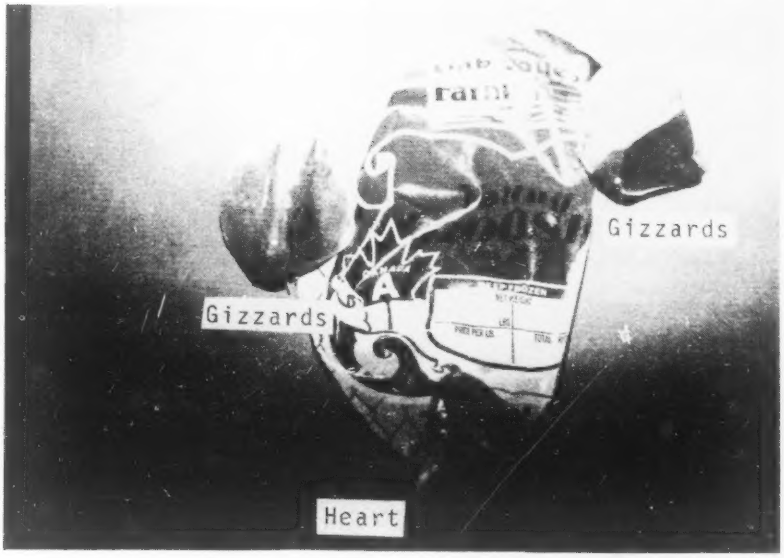

Gizzards
Gizzards
Heart

EXHIBIT "E"

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

1990 MAY 30 AM 9 36

May 25, 1990

Honorable Thomas Daschle
United States Senate
Washington, DC 20510

Dear Senator Daschle:

Thank you for your followup letter concerning the labeling of imported geese from Canada and the open border experiment with Canada.

On the matter of labeling of Canadian geese, in December and January compliance officers of the Food Safety and Inspection Service visited eight of the establishments on the list you enclosed. The other establishments on that list—Ashland Cold Storage in Chicago, Illinois, and cold storage houses in Los Angeles and Oakland—were not identified originally for investigation and were not visited by compliance officers.

During the visits, the officers were looking for geese that carried Canadian grade markings, and they found that three of the establishments did not have such product. Because Canadian grade standards for geese are somewhat different from American grade standards, managers of the other five establishments were offered several ways to handle the product they had. They could have the product recertified to meet U.S. grade standards, return the product directly to Canada, or remove the Canadian grade markings. The managers of two establishments chose to return a total of 994 cartons to Canada; managers of three establishments elected to remove the grade markings from a total of 521 cartons of product. As a result of our investigation, we believe we have ensured that the geese were properly labeled.

With regard to the open border experiment, as I said in a May 3 letter to you, each country will continue to operate label approval programs to assure that differences in standards are handled satisfactorily. Grading standards will be handled in a similar manner. Canada has been provided with the U.S. grading standards, and inspection officials have indicated that they will ensure that product exported to the United States meets these standards.

We appreciate hearing from you on these matters.

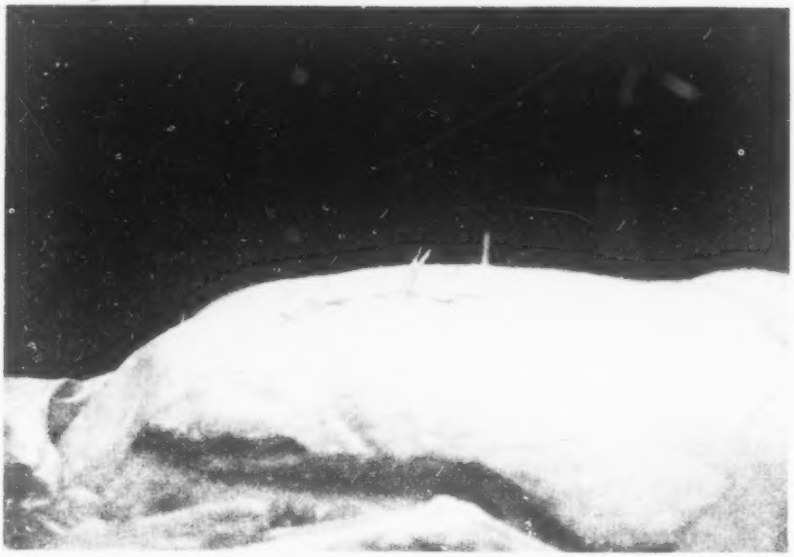
Sincerely,

JoAnn R Smith

Jo Ann R. Smith
Assistant Secretary
Marketing and Inspection Services

EXHIBIT "F"

Picture One



Picture Two

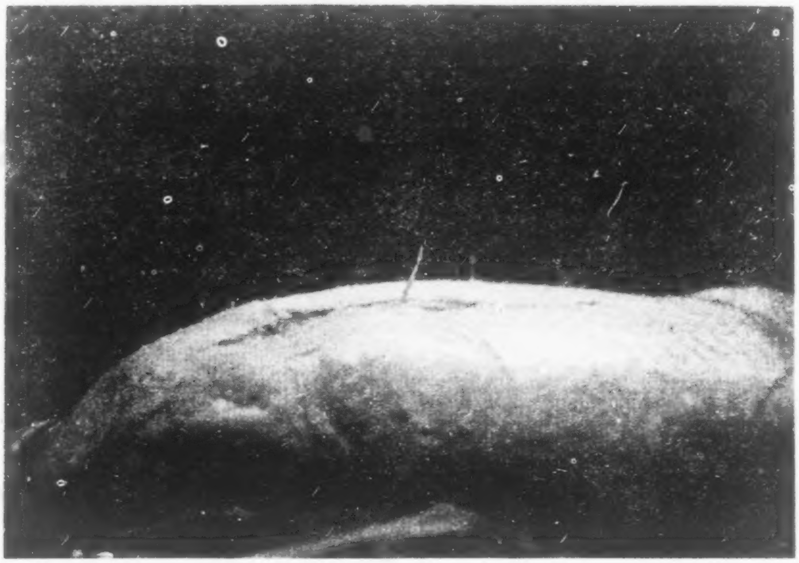


EXHIBIT "G"
(page 1 of 2)

SWANBERG & Company, Inc.
PACKERS • DISTRIBUTORS • EXPORTERS • MERCHANDISERS
P O BOX 156 • STANFORDVILLE, N Y 12581 • (914) 868-7000

JULY 8, 1990

SENATOR THOMAS DASCHLE
CHAIRMAN
SENATE SUBCOMITTEE ON AGRICULTURAL AFFAIRS
WASHINGTON C. C.

DEAR SENATOR DASCHLE:

I HAVE BEEN CONTACTED BY SCHILTZ FOODS, INC., OF SISSETON, SOUTH DAKOTA, TO COMMENT UPON THE PROPOSED REGULATIONS THAT WOULD ALLOW CANADIAN GOOSE PRODUCTS TO BE MARKETED IN THE UNITED STATES WITH NO FURTHER INSPECTION OR GRADING BY THE USDA. I WOULD LIKE TO GO ON RECORD AS BEING TOTALLY OPPOSED TO THE SAME.

SENATOR DASCHLE, FOR THE PAST FORTY-TWO YEARS I HAVE BEEN INVOLVED IN THE MARKETING OF POULTRY PRODUCTS IN THE NORTHEASTERN UNITED STATES. MY GENERAL SALES AREA WAS IN A TRIANGLE FROM BUFFALO, NEW YORK, EAST TO BOSTON, MASSACHUSETTS, AND THEN SOUTH TO WASHINGTON, D.C. MY MAIN OFFICE WAS IN NEW YORK AND FROM THIS OFFICE I MARKETED POULTRY PRODUCTS IN AN AREA THAT HAS A POPULATION OF APPROXIMATELY FORTY MILLION PEOPLE.

THE AMERICAN CONSUMER HAS BEEN RAISED TO BELIEVE THAT THE BEST POULTRY PRODUCT IS A USDA GRADE "A" PRODUCT. THAT WAS THE BEST TYPE OF GOOSE PRODUCT AVAILABLE UNTIL APPROXIMATELY SEVEN YEARS AGO WHEN THE CANADIANS BEGAN FLOODING OUR MARKETS WITH A CANADIAN GRADE "A" PRODUCT. TO THE AMERICAN CONSUMER AN "A" GRADE PRODUCT IS AN "A" GRADE PRODUCT AND IT IS THEIR BELIEF THAT THE CANADIAN GRADING PROCESS IS THE SAME AS THE USDA GRADING PROCESS. NOTHING CAN BE FURTHER FROM THE TRUTH.

IT IS OBVIOUS TO ME, FROM MY 40 PLUS YEARS OF EXPERIENCE, THAT THE CANADIAN GRADE "A" PRODUCT IS NOT THE SAME QUALITY AS THE USDA GRADE "A" PRODUCT. I HAVE PERSONALLY DEFROSTED AND INSPECTED BOTH CANADIAN AND AMERICAN GOOSE PRODUCTS AND FOUND MANY FAULTS AND FAILURES IN THE CANADIAN PRODUCT THAT WOULD NOT BE ALLOWED BY OUR USDA GRADERS.

THE SAD THING, SENATOR, IS THAT THE AMERICAN CONSUMER THINKS SHE IS GETTING AN "A" GRADE PRODUCT WHEN IN FACT SHE IS GETTING A GRADE "B" PRODUCT. FURTHER, SHE THINKS SHE IS PAYING A CHEAPER PRICE AND GETTING THE SAME QUALITY, BECAUSE THE CANADIAN PRODUCT IS CHEAPER AND IT IS OBVIOUS WHY IT IS CHEAPER. THERE ARE TWO REASONS, THE FIRST BEING THAT THE COST OF PRODUCTION HAS TO BE LOWER BECAUSE THE QUALITY IS NOT THERE, AND, SECOND THE EXCHANGE RATE.

EXHIBIT "G"
(page 2 of 2)

PAGE 2-SENATOR DASCHLE-JULY 8, 1990

WHAT IS NEEDED IS INCREASED INSPECTION AND GRADING OF THIS PRODUCT BEFORE IT HITS THE AMERICAN MARKET. ALL CANADIAN PRODUCTS SHOULD HAVE TO MEET THE AMERICAN USDA STANDARDS AS TO GRADING BEFORE THEY ARE ALLOWED TO BE MARKETED AS GRADE "A" PRODUCTS. THIS CAN BE ACHIEVED BY EITHER (1) INSPECTION AND GRADING AT THE BORDER BEFORE THEY ENTER THE COUNTRY OR (2) REQUIRING CANADIAN PRODUCTION PLANTS TO HAVE A CERTIFIED USDA GRADER UPON THEIR PREMISES INSPECTING AND GRADING THEIR PRODUCTS BEFORE IT LEAVES THEIR PLANT AND INTO THE U.S. MARKET.

I WANT TO THANK YOU FOR THIS OPPORTUNITY TO COMMENT UPON THIS.

YOURS TRULY,

Don Swanberg

DON SWANBERG

PREPARED STATEMENT OF GLENN MULLER, PRESIDENT, SOUTH DAKOTA PORK PRODUCERS COUNCIL, DAVIS, SD, ON BEHALF OF THE NATIONAL PORK PRODUCERS COUNCIL (NPPC)

Mr. Chairman and members of the subcommittee:

Thank you for the opportunity to testify before you concerning the meat and poultry inspection agreements between the United States and Canada. My name is Glenn Muller, and I raise hogs on my farm near Davis, South Dakota. I am also the current president of the South Dakota Pork Producers Council.

Today, I speak on behalf of the National Pork Producers Council (NPPC), which represents nearly 100,000 pork producers and their families in the 45 States that are affiliated with the national organization. NPPC is one of the largest dues-paying commodity organizations in the United States. Our members are responsible for more than 90 percent of this country's commercial pork production.

We applaud you for holding a hearing on the pending proposal to establish an open border for meat and poultry trade between the United States and Canada. This hearing is extremely timely in light of the recent publication of the proposed implementing regulations in the Federal Register on June 29, 1990, and the release of a General Accounting Office (GAO) study on this issue on July 6, 1990.

Hearings such as this help ensure that the public's best interest supersedes all other goals. NPPC is vitally interested in this border inspection program because Canada shipped 629 million pounds of hogs, along with fresh, chilled and frozen pork, to the United States last year.

This proposal to eliminate border inspection must accomplish two important tasks. First, it should allow for the continuation of a safe food supply for all people. This is NPPC's highest priority. Second, the proposal can allow the United States and Canada to test new trading arrangements. This program can serve as a laboratory for many future agreements that will benefit U.S. citizens as well as pork producers by encouraging the U.S. economy with more export opportunities around the globe.

FOOD SAFETY ASSURANCES

The United States has developed one of the best meat inspection programs in the world. The similarity of our program to Canada's should help increase our confidence that consumers will receive safe and wholesome meat products.

However, we do not believe that the Food Safety and Inspection Service (FSIS) should in any way abrogate its responsibility or efforts to assure maintenance of equivalency in our two meat inspection systems. Point-of-destination inspections will help provide a safeguard that Canadian product is acceptable. But it may prove inadequate over time if we don't take advantage of opportunities to monitor the Canadian inspection system at point-of-origin in Canada.

As I mentioned previously, providing a safe food supply is NPPC's leading concern. The wholesomeness of the food supply must never be sacrificed in the name of free trade.

Nor should we allow the reputation of U.S. pork producers to be tarnished by permitting poor quality or unwholesome meat to reach the public's plates. Under this new program, American consumers will not be able to tell the difference between most of the pork that will enter this country from Canada and domestically produced meat.

The GAO report raises some valid questions concerning unexplained rejection rates for Canadian meat products in 1989. We believe that it is imperative for us to critically assess the current status of the Canadian meat inspection system before we wholly accept and embrace their system as sufficiently equivalent to our own. As stated by GAO, "we believe FSIS needs to clearly demonstrate and document that American consumers can rely on the Canadian inspection system to guard against contaminated meat under an open border."

Our own U.S. pork producers are working diligently to make sure that their meat is free of drug residues through our Pork Quality Assurance Program that we launched in June of 1989. More than 15 million hogs, or about 18 percent of the U.S. annual production, are now produced by farmers enrolled in this program. These producers are going through a verification program to update themselves on proper drug use, drug withdrawal times and more. We believe this effort demonstrates our commitment to a wholesome food supply.

Because of our emphasis on food safety, we ask that the new inspection program's 1-year trial period also be a period of intensive review. During the 1-year trial, USDA should periodically conduct thorough reviews of the program for any residue or other food quality problems. To facilitate this, USDA should closely monitor packing plants in Canada and point-of-destination inspections.

We encourage USDA to appoint a panel of industry, consumer and government representatives to assist in evaluating the 1-year trial program. Such a panel could use its expertise to help make sure that every step is taken to make the inspection program succeed. The presence of an oversight panel should also increase consumer confidence in the new border inspection agreement. They could also provide guidance in establishing a permanent bilateral inspection program between the United States and Canada. On the other hand, such a panel should not be used to replace day-to-day inspection functions and oversight responsibilities of FSIS.

NPPC is also concerned that Canada permits the use of two drugs that are not approved in the United States. In Canada, the products, Dimetridazole and Ipronidazole, are used to treat livestock and poultry diseases. Yet, our own Food and Drug Administration has not approved the products, and it is believed they may cause cancer. Because of the questions associated with these drugs, NPPC believes that Canada should discontinue the use of these drugs. In the interim, USDA may need to implement routine testing procedures for residues from Dimetridazole and Ipronidazole in the imported meat supply.

IMPLEMENTATION OF AGREEMENT

GAO also raises questions concerning the legal authority to proceed with implementing an open border inspection system. These issues will need to be resolved, along with the physical details of how this new process will work.

It may be appropriate for FSIS to conduct a briefing to outline the details of the system as proposed in the implementing regulation. For example, section 381.198(f)(4) of the proposed regulation states "when there is no United States inspector present at the border, and the joint form does not accompany the product to the border, the product shall be entered." There may be good justification for this proviso, but it's an example of why we need further elaboration of the proposal.

CONCLUSION

NPPC is appreciative for the opportunity to provide these views on the proposed meat and poultry inspection agreement between the United States and Canada. Please call upon our organization if we may provide further input or assistance on this significant change in meat inspection between our two countries. We look forward to working with our Canadian neighbors in the development of a meat inspection system that assures U.S. and Canadian consumers that the food they eat is the safest in the world.

PREPARED STATEMENT OF JACK R. PERRAULT, PRESIDENT, USCBIA, UNITED STATES-CANADA BORDER INSPECTION ASSOCIATION

INTERNATIONAL IMPORT INSPECTION SERVICE

Mr. Chairman and Members of the Subcommittee:

My name is Jack Perrault and I am an owner of a "USDA approved" meat inspection station at Eastport, Idaho along with my partner Gene Duncan. We provide the facilities and manpower to conduct meat reinspection entering the United States from Canada. We have a USDA meat inspector who performs the meat reinspection and either approves or rejects the Canadian meat product entry into the United States. We opened our facility on December 27, 1989, after much encouragement by the FSIS division of the USDA.

I am also a spokesman for a group of fellow Inspection House owners located along the U.S.-Canadian border. Our group has many concerns with regards to the proposed elimination of meat reinspection.

Number one of which is consumer protection. It is the primary responsibility of the USDA to ensure the U.S. consumer that the food he ingests is good, clean, wholesome food. We strongly question the wisdom of our USDA to abrogate this responsibility to another country. The question of equality is of minor importance compared to the responsibility question! Our consumers pay U.S. officials to represent them and not members of another nation. Should we allow this proposal to become operational, a precedent of major proportion will have been set.

We also question the wisdom of such a proposal in light of the rejection rates of Canadian meat imports of 1989 as noted in the recent GAO report. Three percent is an alarming number of rejections, especially when the system allows the Canadians to pick the samples to be reinspected. Eight percent is even more alarming and possibly more representative of the Canadian product, since this is the rate of rejection when the U.S. inspector picks the samples. This statistic is reason enough to continue meat reinspections between our two countries.

We also would like to question the legality of this proposal. It would appear that the USDA thinks the FTA signed with Canada takes precedent over the current laws of our country.

Meat reinspection is the only real safety check under the current system. The USDA has gone from meat reinspection of all product to the current streamlined reinspection system which diminishes the safety checks. Now it wants to eliminate reinspection altogether and put zero checks on the meat industry. Consumer Beware!

Thank you very much for the opportunity to make our views known to you. We would be very happy to share any information you should request from us concerning reinspection procedures, both past and present. Please contact me if we can be of service.

American Association of Meat Processors,
P.O. Box 269, Elizabethtown, PA,
July 12, 1990.

The Honorable Thomas A. Daschle,
Chairman, Senate Agriculture Subcommittee on Agricultural Research and General Legislation, 332 Russell Building, Washington, DC.

Dear Senator Daschle: The American Association of Meat Processors (AAMP) is pleased to provide comments concerning the import/export of meat and poultry products under the United States-Canada Free-Trade Agreement. AAMP, which was founded in 1939, represents over 1,900 companies engaged in meat packing, processing, distribution and retail sales. They are located predominantly in the United States, with other members located throughout Canada and six European countries. AAMP is also affiliated with 31 State and regional meat trade organizations, including the Ontario Meat Processors Association and the Saskatchewan Meat Processors Association.

We strongly support the United States-Canada Free-Trade Agreement, and note that meat and poultry product sales are increasing between both countries. There has been much controversy expressed about the Free-Trade Agreement as it relates to meat and poultry sales, but we are convinced such an agreement was **long** overdue.

We represent meat companies on both sides of the border, and inspection stations, and have been working to help foster communication and a fair resolution of the different concerns between them. We are scheduling a meeting in Nashville the last week of July between AAMP members representing the **Montana Assn. of Meat Processors, the Tri-State Assn. of Meat Processors (MN, ND, SD), the Ontario Meat Processors Assn., the Saskatchewan Meat Processors Assn.**, members engaged in border inspection activities and others to discuss concerns about the movement of meat and meat products between the two countries. This meeting will be in conjunction with the 51st American Convention of Meat Processors, July 26–29, at the Opryland Hotel.

In the past, shipping meat across the border in either direction was often as easy or tough as the current political situation in both countries, which made it tough for everyone. This agreement was intended to eliminate politics, and let people do business on both sides of the border with their country's biggest trading partner. As far as I am aware, the agreement is working satisfactorily, except for the lost inspection business experienced by the border stations. We do recommend that random spot check sampling be continued at some level on both sides of the border to ensure the integrity of the product—at least in the short term, until the new, experimental system has proven itself.

We believe that there should be an advisory or monitoring-working group established between interested groups on both sides of the border to serve as a means to identify and address problems and concerns over the administration of the flow of meat and poultry exports/imports. This advisory group should include not only Federal (Canada and United States) inspected companies, but other buyers and sellers of meat and poultry as well, such as retailers, State-inspected (United States) and provincially (Canada) inspected firms. We note that the import/exports sales are growing for the following reasons—**quality of product, price, and availability.**

There is no question the border inspection station owners have a legitimate complaint about being told by USDA their operations would continue after the United States-Canada Free-Trade Agreement was signed. The border stations should be (in my view) compensated for building the facilities based on USDA assurances.

Unfortunately, because the border inspection stations have been relatively unsuccessful in obtaining compensation through Congress or in reversing the inspection system changes, they have used more extreme tactics. Those tactics, also voiced by unionized meat inspection personnel who are possibly motivated through fear of loss of jobs, include a charge that the meat industry cannot be trusted to ship wholesome meat and meat products across both sides of the border, and that consumer health could be jeopardized. Charges like that hurt everyone in the meat industry, even those who are sympathetic to their problem.

Canadian shippers and border inspection operations have similar complaints about increased charges and unfair treatment by the U.S. border inspection stations and inspection personnel.

Again, **they should be compensated for their dilemma, but not at the expense of U.S. companies seeking to buy Canadian product or shipping U.S. product to Canada.**

In all fairness to USDA, I believe the assurances given at the time to the border inspection stations were true at the time, but the negotiators for the free trade agreement didn't consult with USDA about their decision to ease meat import/export activities. As a result, USDA officials had to develop new regulations with a lessened need for border inspection.

The key concern on this issue should be sanitation, random checks by U.S. and Canadian officials to ensure the integrity of the products, and recognition of the equality of Federal inspection on both sides of the border. If these issues can be adequately addressed, then the meat industry and consumers will be best served.

Respectfully submitted,

JOHN J. AUCIELLO,
Assistant Executive Director.

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
Washington, DC, September 4, 1990.

The Honorable THOMAS A. DASCHLE,
Chairman, Subcommittee on Agricultural Research and General Legislation, Committee on Agriculture, U.S. Senate, Washington, DC.

DEAR SENATOR DASCHLE: Enclosed you will find responses to the questions submitted with your letter of August 2, 1990. I hope the information is useful and responds to your interest in the open border issue.

Sincerely,

JOHN E. FRYDENLUND.
(For) JO ANN R. SMITH,
Assistant Secretary,
Marketing and Inspection Services.

Enclosures.

RESPONSES TO QUESTIONS SUBMITTED BY SENATOR DASCHLE

Question 1. Please provide what information you have on the Listeria issue with regard to the Canadian inspection system.

Response. When improved controls for *Listeria monocytogenes* were instituted in the USDA inspection program, eligible exporting countries were informed of their obligation to implement equivalent controls on similar product exported to the United States. Port of entry testing was initiated in September 1987. POE testing enables FSIS to check on the effectiveness of controls being implemented in other countries.

Listeria m. controls assumed increased priority in the United States following an incident in which an elderly patient's consumption of *Listeria m.* tainted turkey franks preceded her death. The association was not definitely established as causal; however, it was the first occasion in which consumption of a meat or poultry product was associated with a fatality linked to *Listeria m.* The incident which occurred in the United States was very similar to the incident you referenced in connection with your questions, in which a Canadian consumer death was associated with *Listeria m.* contaminated product. Attachment A includes materials describing the U.S.

incident. Attachment B is correspondence from Agriculture Canada which provides details on the Canadian incident.

Question 2. What actions did USDA take in response to these incidences of Listeria contamination?

Response. Listeria testing of Canadian product began in April 1990, and 18 samples were planned for 1990 POE testing. Since this testing began, there have been five instances in which positive *Listeria m.* findings have been recorded. A chronology of events for the positive findings is attached with relevant background material for each (attachment C).

Following all positive findings except the first, hold and test procedures have been applied. This means that there must be 15 consecutive shipments of product which have been tested and found negative for *Listeria m.* before streamlined procedures can be reinstituted for the Canadian origin establishment. In addition, FSIS has increased the sampling plan for all Canadian product for the year 1990 to 56.

Question 3. Was any effort made to require Canada to tighten its procedures to detect Listeria contamination?

Response. FSIS was able to accept Canadian procedures as operationally equivalent, although not identical, as long as POE testing of Canadian product did not disclose a problem. When POE testing and positive findings did disclose a problem, the FSIS position changed, as reflected in correspondence included as attachment D. No further information has been provided by Agriculture Canada about changes in its domestic program.

Question 4. What procedures does the United States employ to detect Listeria contamination and to prevent food products from being sold that might be so contaminated?

Response. U.S. procedures are detailed in the Directive dated February 3, 1989. A copy is provided as attachment E.

Question 5. What procedures does the Canadian Government employ?

Response. Canadian procedures supplied to FSIS in 1990 are detailed in attachment F.

Question 6. Are there any differences in the United States and Canadian procedures with regard to the detection of Listeria contamination?

Response. Comments on the differences in the procedures of the two systems are provided in correspondence included in attachment G.

[Attachments A–G follow:]

ATTACHMENT A

Morbidity and Mortality Weekly Report
Thursday April 20, 1989

Epidemiologic Notes and Reports

Listeriosis Associated with Consumption of Turkey Franks

Microbiologic implication of meat as a source of clinical listeriosis has not previously been documented. In December 1988, a woman with cancer was hospitalized in Oklahoma with sepsis caused by Listeria monocytogenes (LM). LM was isolated from an open package of Plantation Brand turkey franks from the patient's refrigerator. The patient had eaten one turkey frank daily heated in a microwave oven. LM was also isolated from two unopened packages of Plantation Brand turkey franks from a local store. Cultures of other foods in the patient's refrigerator were positive for LM; however, unopened samples of those foods were negative for LM.

LM isolates from the patient and from the opened and unopened packages of franks were confirmed at CDC as serotype 1/2a with the same electrophoretic enzyme type. On April 14, 1989, the company voluntarily recalled the franks, and the U.S. Department of Agriculture began an investigation of the processing plant.

Multiple products from the patient's refrigerator grew LM of the same serotype and enzyme type, suggesting cross-contamination; therefore, isolation of LM from opened packages is not sufficient to identify the source of infection. Isolation from unopened products implicates the source of infection with greater certainty.

An epidemiologic study of dietary risk factors for sporadic cases of listeriosis previously implicated consumption of uncooked hot dogs and undercooked chicken (1); in that study, no microbiologic specimens were obtained.

LM causes 1700 cases of meningitis and sepsis in the United States each year, with a case-fatality rate of 25%. Listeriosis usually occurs in pregnant women or immunosuppressed persons. Such persons who have eaten this brand of turkey franks and are not ill do not need treatment. Persons who have eaten this food and develop fever, severe headache, or muscle aches should consult their physicians.

Reported by: R Barnes, P Archer, MPH, J Strack, GR Istre, MD, State Epidemiologist, Oklahoma State Dept of Health. Meningitis and Special Pathogens Br, Div of Bacterial Diseases, Center for Infectious Diseases, CDC.

Reference

1. Schwartz B, Cielsielski C, Broome CV, et al. Dietary risk factors for sporadic listeriosis: association with consumption of uncooked hot dogs and undercooked chicken. Lancet 1988;2:779-82.

United States Department of Agriculture

Food Safety and Inspection Service

9 MAY 1989

To: Ralph W. Johnston, Director
Microbiology Division, Science

From: Stanley S. Green, Chief Stanley S. Green
MMSB, MD, Science

Subject: Plant Visit - P-635 - Plantation Foods

Information from the Centers for Disease Control (CDC) relating to a human case of listeriosis was received by FSIS and the Microbiology Division late Friday afternoon, April 14, 1989. The reported human illness prompted an immediate investigation by FSIS and a visit to the plant that produced the turkey franks implicated in the incident - Plantation Foods, 3130 Gholson Road, Waco, Texas. Southwest Regional personnel and a member of the CDC staff would also visit the plant.

All processing areas directly involved with the production at Plantation Foods were reviewed by MPIO field personnel and will be addressed in a separate report (Enclosure 1). The necessary requirements needed to be completed by plant management prior to resumption of turkey frank production were provided to management by Mr. H. Bentsen (Enclosure 2). A letter of response to the IIC was submitted on April 17, 1988 (Enclosure 3).

This report addresses only the turkey frank processing and packaging operation as seen and reviewed by the representative from the Microbiology Division, Washington, D.C.

Case Background

The following information regarding the human illness was learned from Dr. Jay Wenger, CDC.

FSIS 2630-5 (12/79)

The CDC has an ongoing human listeriosis surveillance program in Oklahoma, four counties in Tennessee, and the metropolitan areas of San Francisco and Los Angeles, California and Atlanta, Georgia (approximately 18 million people). This case of listeriosis was reported to CDC by the State of Oklahoma as a requirement of reportable diseases and the surveillance program.

A female patient (61 years) from Skiatook, Oklahoma, was admitted to the hospital with fever and infection, December 8, 1988. Cultures were taken for bacterial isolation and identification upon hospital admission. The patient with a prior diagnosed condition of breast cancer as a predisposing factor succumbed four weeks after admission (January 6, 1989). Listeria monocytogenes serotype 1/2a was identified by the hospital clinical laboratory. The cause of death was listed as cancer.

The Oklahoma State Department of Health was asked by CDC to collect all foods from the refrigerator at the patient's home. An open package of turkey franks, sell by November 18, 1988, produced by Plantation Foods (P-635) was collected and analyzed at CDC. This sample was positive for L. monocytogenes 1/2a by direct plate and at a level of greater than 1100 cfu/gm. Two packages purchased in Oklahoma City and analyzed by CDC were negative for Listeria (sell by date (March 10; March 13, 1989)). Three unopened packages of turkey franks were purchased in the vicinity of Skiatook, OK, in March 1989, by the Oklahoma Department of Health. Two packages (sell by date, January 13) analyzed at CDC were positive for L. monocytogenes serotype 1/2a by enrichment; (direct plate results - unknown). The third package with the sell by January 13 date arrived at CDC on April 19, 1989, (analysis pending). Electrophoretic enzyme tests by CDC of each Listeria isolate (patient, open-package, and two closed packaged) were identical.

Establishment P-635

A preliminary meeting and briefing was held Saturday morning, (April 15, 1989), upon arrival at Plantation Foods. The following individuals and their affiliations, were present during all or portions of the meeting.

Plantation Foods

Richard Taylor - President
Earl Tooker - Plant Manager

FSIS

Dr. E. Humphries - Regional Poultry Coordinator
Dr. V. Coiner - Area Supervisor
D. J. Puttey - IIC
Frank Nickolas - Food Technologist
J. Bilbo - Inspector - Night Shift
K. Goin - Compliance
H. Bentsen - Circuit Supervisor
Dr. S. Green - MD, Washington, DC

CDC

Dr. J. Wenger - Meningitis and Special Pathogens Branch

A brief case history was presented by Dr. Wenger, CDC, and the time frames of the investigation. Additional details as to age of product, laboratory results regarding enumeration of *L. monocytogenes*, etc., were provided by CDC. FSIS representatives presented to plant management the proposed plan as outlined in the FSIS Directive 10,240.1, *Listeria monocytogenes*; Testing Procedures and Sanitation Information (2/3/89). From the perspective of the Microbiology Division, I outlined my activities as they would occur at Plantation Foods and answered Mr. Taylor's questions about our recent *Listeria* testing programs. I informed those present that programs were in place for both raw and most ready-to-eat products and to the best of my recollection, the number of *Listeria monocytogenes* positive monitoring samples for ready-to-eat products. The individuals present were receptive to all the information provided and assured FSIS that plant management would cooperate to the fullest extent.

Plant Facilities

Plantation Foods is a totally integrated turkey operation. The firm is involved in the grow-out of the turkeys on both owned and contracted farms, providing the poults, feed, veterinary services, and all ancillary functions including transportation of birds to slaughter.

The turkeys (both toms and hens) are brought to the slaughter plant (erected 1965) and proceed through a typical turkey slaughter operation. The partially chilled carcasses (80-85°F) upon exiting the chill tank, immediately proceed to a boning room. This whole process could almost be considered a "hot boning" operation. Live bird to parts, occurs in approximately 45 minutes. Most of the turkey parts move to various areas of the plant for further processing into completely cooked product lines ranging from uncured, cooked, turkey breasts through cured, cooked products such as turkey ham, bologna, salami, pastrami, etc. The deboned carcass is moved to a mechanical deboning line that course grinds the material prior to entering a beehive type deboner. Upon exiting the heat exchanger (contherm), other ingredients are added (spices, flavorings, erythorbate and nitrite) to the chilled mechanically deboned material to prepare the turkey franks. Some raw turkey parts are tray packaged (drum sticks, wings) for retail sale but these are a limited item. The majority of the turkey processed ultimately is cooked at the plant. Some chicken products are prepared at Plantation from purchased chicken that is fabricated into cooked nuggets, tenders. etc.

Observations Related to Turkey Frank Operations

Processing operations were terminated at COB Friday, 4/14/89, upon notification by region and/or communication with MPIO, Washington, D.C. Information related to turkey frank processing was primarily verbal and provided by FSIS and plant personnel. Direct observations on Monday morning, 4/17/89, provided the remainder. Environmental and product samples were collected on Saturday, 4/15/89, and Monday, 4/17/89 (Enclosure 4).

There were several areas during the process at which finished franks could possibly contact raw product. The typical flow of raw franks to package, proceeds in the following manner:

1. Emulsion-stuffed, linked, coiled and hung on smoke racks.
2. Smoke rack - fork lifted through door in raw product area directly to cooking area.
3. Smoke rack - placed in smokehouse by fork lift.

4. Cook cycle begins

Dry Bulb	Wet Bulb	Time	Smoke
140°F	-	15 min	1 min
155°F	125°F	15 min	No
180°F	155°F	To IT 172°F	No

5. After cook - showered for 5 minutes, (city water) to approximately 100°F.

6. Smoke rack - removed from smokehouse with same or similar fork lift that placed raw franks into smokehouse.

7. Smoke rack of cooked franks covered with clear plastic shroud and moved to cooler by fork lift.

8. Franks - Chilled overnight. Removed from cooler with either manual or motorized fork lift and brought to peeler operation.

9. Franks - Plastic shroud opened, franks sprayed with city or well water (depends on water available at that time).

10. Moistened franks - Hand fed (gloved employee) to peeler and conveyed to either bulk package (10 lbs) or to tubs for transport to Multivac equipment and retail packaging line.

11. Bulk Package - Vacuum drawn and product frozen. Consumer product is packaged by Multivac equipment. Consumer sized packages are keep-refrigerated with a shelf life of 56 days. Sell by date is calculated by adding 56 days to the Julien date of production day.

Major concerns related to turkey frank processing/packaging:

- Proximity of raw product area to cooking area.
- Common fork lift or equipment moving raw product and cooked products in cooking area.

- Large fans constantly moving air across the face of smokehouses. Air flow was from raw area past door face of ovens.

- Aluminum peeler head was pitted and valves were leaking, offering areas and moisture for possible bacterial/Listeria growth.

- Condensate in exposed cooked product (franks) areas that could support growth of Listeria.

  a) Turkey frank packaging room.

  b) Underside of metal ceiling over smokehouse area. Fans mentioned earlier move air along and under this overhang).

cc:
M. A. Norcross, SCI, Wash., DC
W. H. Dubbert, SCI, Wash., DC
M. Mina, IMP, Wash., DC
P. Tancredi, IMP, Wash., DC
E. Montgomery, EP, Wash., DC
M. Waguespack, SWRO, Dallas, TX
E. Humphries, SWRO, Dallas, TX
D. V. Coiner, Area Supervisor, Dallas, TX
J. Puttey, IIC, P-635, Waco, TX
F. Nickolas - Food Technologist, P-635, Waco, TX
H. Bentsen, Circuit Supervisor, SWRO

Enclosure 1

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Meat and
Poultry
Inspection
Operations

Southwestern Region
1100 Commerce Street
Room 5F41
Dallas, TX 75242

To: Dr. Moise Waguespack, Director
Southwestern Region

April 21, 1989

HEB

From: Harold E. Bentsen, Circuit Supervisor
Fort Worth, Texas

Subject: Investigation of Listeria Findings at Establishment P-635, Plantation Foods, Inc.

On Friday, April 14, 1989, the Southwestern Region was notified of a positive finding of Listeria monocytogenes in turkey frankfurters processed by Establishment P-635, Plantation Foods, Inc., Waco, Texas.

I arrived at Establishment P-635 at 0745 on Saturday, April 14. Dr. Stanley Green, Branch Chief, Microbiological Monitoring and Surveillance Branch, Science, and Dr. J. D. Wenger, Medical Epidemiologist, Meningitis and Special Pathogens Branch, Centers for Disease Control, were already at the plant meeting with Dr. Humphries, Dr. Coiner, Dr. Putty, Inspectors Nicholas and Bilbo, and Messrs. Taylor and Tooker of Plantation Foods.

After a discussion of Listeria concerns in general, and the specific implications of the positive findings in Plantation Foods' product, we received assurances of full cooperation from both Mr. Taylor, president of the company, and Mr. Tooker, plant manager.

A brief familiarization tour of the plant was conducted with special emphasis given to the areas where cooked and exposed cooked products are handled. No operations were conducted on Saturday, but Doctors Green and Wenger were able to collect swab samples of a variety of equipment surfaces, product contact areas and walls, as well as some previously prepared product which was still on hand.

I met with Mr. Taylor and Mr. Tooker and discussed the provisions of FSIS Directive 10,240.1 with particular emphasis placed on the sanitation information attachment on pages 8 through 14. They asked for additional time to prepare their action plan and proposed immediate implementation of interim corrective measures in order to resume operations in cooked product areas as soon as possible. I consulted with Dr. Nelson regarding the company's proposal and received authorization to establish a list of minimum requirements.

Drs. Green and Wenger and I returned to the establishment at approximately 1400 hours on Sunday, April 16 to collect additional microbiological samples and to afford Dr. Wenger the opportunity to observe the curing operation then in progress. I prepared a list of nine interim corrective measures to be implemented before operations could be assumed in heat processed product areas (attachment 1). The list was discussed with Mr. Earl Tooker who agreed to all of the provisions and indicated that the required floor to ceiling cleaning and sanitizing was already in progress in most departments. I also requested that the frankfurter packing room not be subjected to any unusual cleaning or sanitizing procedures at this time because the company had approximately 8,000 pounds of emulsion and eight racks of frankfurters still in artificial casings which had been produced prior to our notification of the Listeria findings. Drs. Green and Wenger had hoped to collect samples of these products manufactured under conditions similar to those in effect when the Listeria positive frankfurters were produced last March.

When we arrived at the plant on Monday morning, we were informed that there were no employees on the day shift who could stuff the emulsion. The peeling of the previous production franks was delayed because the IIC had instructed the plant that morning to replace a steam line and valve which were introducing rusty water into the peeler contact areas. Since we had noticed this condition Saturday morning, and because it appeared to be a long-standing condition, we requested the original steam valve and line be reconnected in order to lend validity to the product samples scheduled for collection that day. The previous week's frankfurter emulsion was re-scheduled for stuffing and cooking at 0500 on Tuesday.

On Tuesday morning we were advised that the company had discarded the old emulsion because it had been held too long. They had, however, formulated a new batch of franks and we were able to observe the stuffing and cooking procedures, and Dr. Wenger collected additional emulsion and cooked product samples as well as swab tests of a variety of equipment and contact surfaces. Dr. Green had returned to D.C. on Monday afternoon so additional cooked product samples were collected for him. I advised the IIC that the product produced and sampled on Tuesday would not be considered new production nor would it be credited under the five lot hold and test procedure authorized in Directive 10,240.1.

On Monday and Tuesday, I had the opportunity to observe plant conditions during actual operations. In my opinion, a great deal of work needs to be accomplished in the areas of cleaning and sanitizing, facilities and equipment maintenance, control of condensation, sanitary product handling procedures, personal hygiene and general employee practices. The following list of observations is not all-inclusive, but is intended to illustrate some major areas of concern:

1. Condensation is evident throughout the processing areas of the plant. Where the problem is addressed at all, it is accomplished by installing plastic sheets beneath the affected areas. These sheets frequently become torn or dislodged, allowing collected condensate to escape. Many overhead structures bear remnants of tape and plastic from previous installations.

2. The only hand wash sink I observed in the emulsion room was cluttered with tools and equipment parts. There was no water available at the sink. In the frankfurter pack room, there is one large sink with eight faucets, but there is only one operable dispenser for the hand soap/sanitizing solution.

3. Employees wear disposable plastic gloves in virtually all departments. I observed many instances in which the gloved hands were simply run under running water from a hose, or dipped into still water in an edible product container. It is my impression that gloves are worn primarily to keep the hands clean, rather than to protect the product from contamination.

4. Employees working in contact with exposed heat processed product wear the same outer garments as everyone else in the plant. These garments are not kept in the heat processed product rooms where employees go on lunch or break, and the personnel working in these rooms share both a cafeteria and locker facility with employees from raw product operations. (The cafeteria and locker room are all one area).

5. Rust, corrosion and peeling paint on overhead structures. Heavy accumulations of dust on overhead electrical lines and fixtures. Two air venting closing machines in the large cooked product slice/pack room had cheesecloth filters installed over the air vents. These filters were entirely black from accumulations of trapped dust and impurities and had apparently been in place for quite some time. There is a very strong air movement through these filters.

6. Two metal storage cabinets in the frank pack room contained a mixture of labeling material, machine parts, tools and chemical compounds. The interiors of the cabinets were rusty and corroded.

7. Unused machinery in the frank pack room was covered with heavy duty plastic or rubber coated protective shrouds. These covers were heavily contaminated with meat and fat particles as well as what appeared to be specks of grease and soot. This room is very congested and traffic in these areas poses a potential for contamination. The covered equipment is also used for work tables and box storage.

8. Boxes with plastic liners were nested in a fashion which exposes the liners to contamination. Exposed fully cooked sliced turkey rolls were being bulk-packed in these boxes.

9. Between shift clean-up in the emulsion room is conducted while exposed product is being handled in close proximity to the area being cleaned. The method of cleaning appears to utilize only hot potable water, but the water is delivered under high pressure and no care is taken to protect operational areas.

10. There is a great deal of congestion and backing up of both raw and cooked product. More consideration needs to be given to product flow and production volume.

11. The same fork lift is used to transport product to and from the smokehouse. This creates a high potential for cross contamination.

12. The overhead door between the emulsion room and the smokehouse area does not close properly, allowing a gap of several inches from the floor. This is further complicated by the presence of two heavy duty fans installed in the smokehouse area to prevent warm moist air entering the emulsion room. This creates a significant air flow from a raw to a cooked product area.

13. In the second floor nugget room, turkey rolls were being sliced, conveyed through a blast freezer, and then to a spiral chute which dropped down into the frank pack room. An air hose runs down through the same hole in the floor and very close to exposed product discharged down the chute. Although there is a raised lip around the floor opening, there is a good possibility that equipment and/or product in the frank pack room below could become contamined during clean-up procedures.

14. A mixed use room next to the nugget room is used to store and weigh out spices, store unused equipment and also serves as a maintenance facility. A metal cabinet in this room is in the same condition as the one noted in item 6.

There was a cockroach imbedded in a viscous substance which had either been spilled on the floor, or had seeped under the wall from the nugget room. A live cockroach was also noted in this area.

15. The second floor box storage and assembly room was congested. Some assembled boxes were stored on cardboard directly on the floor. There was no space between rows of pallets to allow access for inspection.

Some corrective action addressing the most critical deficiencies in heat processed handling areas was begun almost immediately. These actions are generally outlined in the April 17 letter from Earl Tooker to Dr. John Putty (Attachment 2). A great deal needs to be accomplished before conditions at this plant can be deemed acceptable. I recommend that when significant progress has been made, we request a return visit from the Microbiological Monitoring and Surveillance Branch so a similar pattern of testing could be conducted in an attempt to measure the effectiveness of our actions.

ATTACHMENT 1

Provisions for Resumption of Operations

1. Thorough floor to ceiling clean-up and sanitizing of all post cook areas. This includes all rooms and traffic areas in which heat processed product is handled or travels.

2. Separate, identifiable outer garments for all personnel handling exposed heat processed products

3. Storage areas in heat processed product rooms for the identified outer garments

4. Foot baths containing sanitizing solutions at all entrances to heat processed product (exposed) handling rooms.

5. Additional attention given to mid-shift clean up and sanitizing in applicable areas.

6. Eliminate use of fork lift to transfer racks of finished cooked product to cooler or use a separate, identified and acceptably maintained vehicle for this purpose.

7. Develop and implement a check-off list for use by establishment personnel during pre-operative sanitation

8. Reaffirm current policy in reaction to condensation.

equipment cleaned & sanitized; exposed product held for disposition.

7. Provide a target date by which the in-depth correcti action plan will be presented to the IIC.
The corrective action plan must address every applica item listed on pages 8 through 14 of FSIS Directive 10,240.1
The corrective action plan should be submitted as soo as possible, but no later than April 28, 1989.

It should be understood that the interim corrective actions/preventive measures outlined above represent minimum precautions implemented in order to reduce the ris of further positive findings of Listeria Monocytogenes in your heat processed products. You should not limit your selves strictly to the topics listed here or in FSIS Directiv 10,240.1. You are encouraged to investigate all possible areas of concern and incorporate these into your final action plan.

ATTACHMENT 2

April 17, 1989

Dr. John Putty
Inspector in Charge
Plantation Foods, Inc.
Box 20788
Waco, TX 76702-0788

Dr. Putty:

According to the provisions given to us by FSIS personnel, we will comply fully in order to resume plant operations.

1. Thorough floor to ceiling clean-up and sanitizing of all post cook areas. This includes all rooms and traffic areas in which ~~exposed~~ heat processed product is handled or trafficked.

2. Separate and identifiable outer garments will be worn by all personnel handling exposed heat processed product.

3. Wall hangers will be provided to store/hang identifiable outer garments in the heat processed work areas.

4. In the laundry room, the outer garments worn by those handling exposed heat processed products will have a separate and identified area for storage.

5. Foot baths containing a sanitizing solution will be appropriately placed so that anyone entering a room where exposed heat processed products are being handled will step into same, sanitizing their footwear.

6. Additional attention will be given to mid-shift and between shift clean-ups and sanitizing in appropriate areas.

7. Forklifts and/or powered tuggers will be so identified so that a given vehicle will only handle raw or cooked product, NEVER both.

8. A check-off list will be used by plant personnel to ensure that thorough clean-up and sanitization procedures have been completed prior to the pre-operative examination by FSIS.

9. Reaffirm the current policy in reaction to condensation. In any area where condensation occurs:
    - a) operations cease
    - b) product removed
    - c) equipment cleaned and sanitized
    - d) exposed product held for disposition
    - e) overhead area temporarily draped with clean plastic sheeting.

10. We will present for approval a complete and comprehensive corrective action plan addressing all items listed on pages 8 through 14 of FSIS Directive 10,240.1 as soon as possible but no later than April 28, 1989.

It is understood that these interim corrective actions and preventative measures listed above represent minimum precautions implemented in order to reduce the risk of further positive findings of Listeria Monocytogenes in our heat processed products. We will investigate all possible areas of concern and incorporate these into our final action plan.

Earl Tooker

Earl Tooker
Plant Manager

P635

cc: Dick Taylor
Roane Lacy, Jr.

ET/tam

Enclosure 2

Provisions for Resumption of Operations (per H. Bentsen)

1. Thorough floor to ceiling clean-up and sanitizing of all post cook areas. This includes all rooms and traffic areas in which heat processed product is handled or travels.
2. Separate, identifiable outer garments for all personnel handling exposed heat processed products.
3. Storage areas in heat processed product rooms for the identified outer garments.
4. Foot baths containing sanitizing solutions at all entrances to heat processed product (exposed) handling rooms.
5. Additional attention given to mid-shift clean-up and sanitizing in applicable areas.
6. Eliminate use of fork lift to transfer racks of finished cooked product to cooler or use a separate identified and acceptably maintained vehicle for this purpose.
7. Develop and implement a check-off list for use by establishment personnel during pre-operative sanitation.
8. Reaffirm current policy in reaction to condensation, i.e., operations in affected area stopped; product removed; equipment cleaned and sanitized; exposed product held for disposition.
9. Provide a target date by which the in-depth corrective action plan will be presented to the IIC. The corrective action plan must address every applicable item listed on pages 8 through 14 of FSIS Directive 10,240.1. The corrective action plan should be submitted as soon as possible, but no later than April 28, 1989.

It should be understood that the interim corrective actions/preventive measures outlined above represent minimum precautions implemented in order to reduce the risk of further positive findings of Listeria monocytogenes in your heat processed products. You should not limit yourselves strictly to the topics listed here or in FSIS Directive 10,240.1. You are encouraged to investigate all possible areas of concern and incorporate these into your final action plan.

Enclosure 3

April 17, 1989

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Inspector in Charge
Plantation Foods, Inc.
Box 20788
Waco, TX 76702-0788

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According to the provisions given to us by FSIS personnel, we will comply fully in order to resume plant operations.

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2. Separate and identifiable outer garments will be worn by all personnel handling exposed heat processed product.

3. Wall hangers will be provided to store/hang identifiable outer garments in the heat processed work areas.

4. In the laundry room, the outer garments worn by those handling exposed heat processed products will have a separate and identified area for storage.

5. Foot baths containing a sanitizing solution will be appropriately placed so that anyone entering a room where exposed heat processed products are being handled will step into same, sanitizing their footwear.

6. Additional attention will be given to mid-shift and between shift clean-ups and sanitizing in appropriate areas.

7. Forklifts and/or powered tuggers will be so identified so that a given vehicle will only handle raw or cooked product, NEVER both.

8. A check-off list will be used by plant personnel to ensure that thorough clean-up and sanitization procedures have been completed prior to the pre-operative examination by FSIS.

9. Reaffirm the current policy in reaction to condensation. In any area where condensation occurs:
   a) operations cease
   b) product removed
   c) equipment cleaned and sanitized
   d) exposed product held for disposition
   e) overhead area temporarily draped with clean plastic sheeting.

10. We will present for approval a complete and comprehensive corrective action plan addressing all items listed on pages 8 through 14 of FSIS Directive 10,240.1 as soon as possible but no later than April 28, 1989.

It is understood that these interim corrective actions and preventative measures listed above represent minimum precautions implemented in order to reduce the risk of further positive findings of Listeria Monocytogenes in our heat processed products. We will investigate all possible areas of concern and incorporate these into our final action plan.

Earl Tooker
Plant Manager

cc: Dick Taylor
Roane Lacy, Jr.

ET/tam

Enclosure 4

Samples collected at Plantation Foods

1. Finished product:

   5 - retail packaged turkey franks 1032*/6012**

   5 - retail packages turkey franks 1042/6012

   5 - retail packages turkey franks 1002/6012

   5 - retail packages turkey franks 0962/6012

   5 - retail packages turkey franks 0872/6009

   2 - 2 pound retail package turkey franks 1021/6008

   10 - retail packages turkey franks 0692/6009

   1 - 10 pound institutional pack 0281***

* Julien date of production. Add 56 days to obtain sell by date.

** Plant product code - refers to last four digits of universal product code.

*** Institutional package produced October 28, 1988, and maintained frozen.

2. Product samples collected during processing:

   3 samples - turkey franks skin on (from cook rack 2 in cooler)

   1 sample turkey franks after peeler - cook rack 1

   1 sample turkey franks after peeler - cook rack 2

   1 sample turkey franks after peeler - cook rack 7

   2 samples cooked turkey franks - from 4/18 processing

   1 sample cooked turkey franks after peeler

3. Environmental swab samples and location:

   Cook rack 1 - finished product cooler

Standing water - finished product cooler

Floor - finished product cooler

Cooling cells - entry frank packaging area

Conveyor belt - post peeler in packaging area

Peeler - before processing - frank packaging area

Tipper tie nozzle - before processing - frank packaging area

Tipper tie nozzle - after processing - frank packaging area

Peeler - after processing - frank processing area

Tipper tie trap - after processing - frank packaging area

Fork lift - cook area

Smokehouse shower nozzles - cook area

Service lines over peeler - frank packaging area

Peeler shroud (exhaust hood) - frank packaging area

Roll stock - frank packaging area

Condensate - frank packaging area

Spina Bifida — Continued

births in rural northern People's Republic of China (*5*), about nine times the total U.S. rate of 4.3/10,000 live births in 1987. Low socioeconomic status has been strongly associated with risk for these defects in many populations. The causes of spina bifida must be identified to design effective primary prevention. These epidemiologic findings suggest that such identification may be possible.

Nutritional status has been widely studied as a risk factor for spina bifida in the last decade. In particular, periconceptional vitamin supplementation in women who previously had had an affected infant was studied in a nonrandomized clinical trial and reported in 1981 to be protective (*6*). However, 95% of all infants with spina bifida are born to women who have never had an affected infant. A CDC case-control study of a large group of these women showed that those who reported using multivitamin supplementation during the periconceptional period had a 50% reduction in the incidence of spina bifida in their children (*7,8*). It cannot yet be determined whether the apparent protective effect associated with multivitamins results directly from multivitamin use or from other characteristics of women who use vitamins. Therefore, the evidence accumulated to date does not support recommendation of a national policy for treating all women at risk for pregnancy with multivitamins. Well-designed randomized clinical trials would be a means to examine the possible protective effect of multivitamin supplementation and to provide the scientific basis for public health policy regarding multivitamin use before pregnancy and during early gestation.

References

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4. Elwood JM, Elwood JH. Epidemiology of anencephalus and spina bifida. Oxford: Oxford University Press, 1980.
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Listeriosis Associated with Consumption of Turkey Franks

In December 1988, a woman with cancer was hospitalized with sepsis caused by *Listeria monocytogenes* (LM). LM was isolated from an open package of Plantation Brand turkey franks from the patient's refrigerator, and from other foods in that refrigerator. The patient ate one turkey frank daily heated in a microwave oven. LM was isolated from two unopened packages of Plantation Brand turkey franks from a local store. Cultures of unopened samples of the other foods in the refrigerator were negative. LM isolates from the patient and from the opened and unopened packages of franks were confirmed at CDC as serotype 1/2a with the same electrophoretic

Spina Bifida — Continued

enzyme type. On April 14, 1989, the company voluntarily recalled the franks, and the U.S. Department of Agriculture began an investigation of the processing plant.

Multiple products from the patient's refrigerator grew LM of the same serotype and enzyme type, suggesting cross-contamination; therefore, isolation of LM from opened packages is not sufficient to identify the source of infection. Isolation from unopened products implicates the source of infection with greater certainty.

Microbiologic implication of meat as a source of clinical listeriosis has not previously been documented. However, an epidemiologic study of dietary risk factors for sporadic cases of listeriosis previously implicated consumption of uncooked hot dogs and undercooked chicken.

LM causes 1700 cases of meningitis and sepsis in the United States each year, with a case-fatality rate of 26%. Listeriosis usually occurs in pregnant women or immunosuppressed persons. Such persons who have eaten this brand of turkey franks and are without symptoms do not need treatment. Persons who have eaten this food and develop fever symptoms should consult their physicians.

Reported by: R Barnes, P Archer, MPH, J Strack, GR Istre, MD, State Epidemiologist, Oklahoma State Dept of Health. Div of Bacterial Diseases, Center for Infectious Diseases, CDC.

[illegible]

Errata: Vol. 38, No. 14

In the article "Tuberculosis and Human Immunodeficiency Virus Infection: Recommendations of the Advisory Committee for the Elimination of Tuberculosis (ACET)," two errors regarding the size of tuberculin skin reactions occurred: 1) on page 243, the second to last line of the second full paragraph should end "*tuberculin reactions of ≥5-mm induration*"; and 2) on page 248, the fifth line from the top of the page should begin "*≥10-mm induration.*"

☆U.S. Government Printing Office: 1989-631-108/81560 Region IV

DEPARTMENT OF
HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control
Atlanta, GA 30333

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HHS Publication No. (CDC) 89-8017

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ATTACHMENT B

Agriculture
Canada

Food Production
and Inspection Branch

Direction générale,
Production et inspection des aliments

Ottawa, Ontario
K1A 0Y9

Your file Votre référence

Our file Notre référence

May 30, 1990

Mr. Wally Kunkel
Plant Manager
Fletcher's Fine Foods Ltd.
8385 Fraser Street
Vancouver, British Columbia
V5X 3X8

Dear Mr. Kunkel:

This letter will confirm our telephone conversation of this date regarding the recent "Food Chemical News" article linking weiners with a case of listeriosis in British Columbia.

As discussed with you, we have been informed by Dr. Jeff Farber, Health Protection Branch, Health and Welfare Canada (Tel: 613 957-0895) that follow-up investigations were not able to directly link this particular case with any food found in the woman's refrigerator. The unopened packages of weiners which were tested by the Health Protection Branch were found to be contaminated with Listeria monocytogenes, however the serotype detected was completely different from the serotype responsible for the woman's illness.

It is the conclusion of Health Protection Branch that cross contamination of foods occurred in the household making it impossible to determine the primary source of the organism.

I trust this information satisfactorily addresses your concerns. If I may be of more assistance, please contact me at (613) 995-5433 Ext. 4666.

Sincerely,

T. Feltmate
Associate Director
Epidemiology and Risk Assessment
  Section
Agri-Food Safety Division

TF/ad

A842-1P
5-31-90

[illegible]

QUESTIONS AND ANSWERS RE LISTERIA IN WEINERS

Q. Is the death of a 64 year old woman linked to weiners produced in a federally inspected establishment?

A. All available evidence from Health and Welfare Canada investigations into this case reveals that there is not a direct link between the woman's death and the presence of Listeria in weiners produced in a federally inspected establishment.

Several foods tested in the woman's refrigerator were found to be contaminated with the specific Listeria serotype responsible for the woman's illness. (Serotyping is a laboratory method used to distinguish between the many different strains of Listeria)

The actual source of the serotype involved was not determined. It is entirely possible that the foods in the refrigerator may have been contaminated by the woman.

Unopened weiners from the registered establishment in question did not contain the same serotype of Listeria as that involved in the illness.

Q. What is Agriculture Canada doing to protect consumers from Listeria in ready-to-eat meats?

A. Agriculture Canada, in collaboration with Health and Welfare Canada, has implemented a new sampling and control strategy specifically designed to reduce the potential for exposure of ready-to-eat meat products to Listeria organisms.

As environmental contamination is considered to be the primary route of exposure for ready-to-eat meats, the thrust of this program will be to reduce or eliminate this source. All establishments producing ready-to-eat meat products will undergo environmental testing to determine if Listeria is present. Those plants found to be positive will undergo an extensive clean-up and sanitation procedure followed by additional environmental testing. Where elimination or reduction is not achieved, product testing and recall, as necessary, will be implemented.

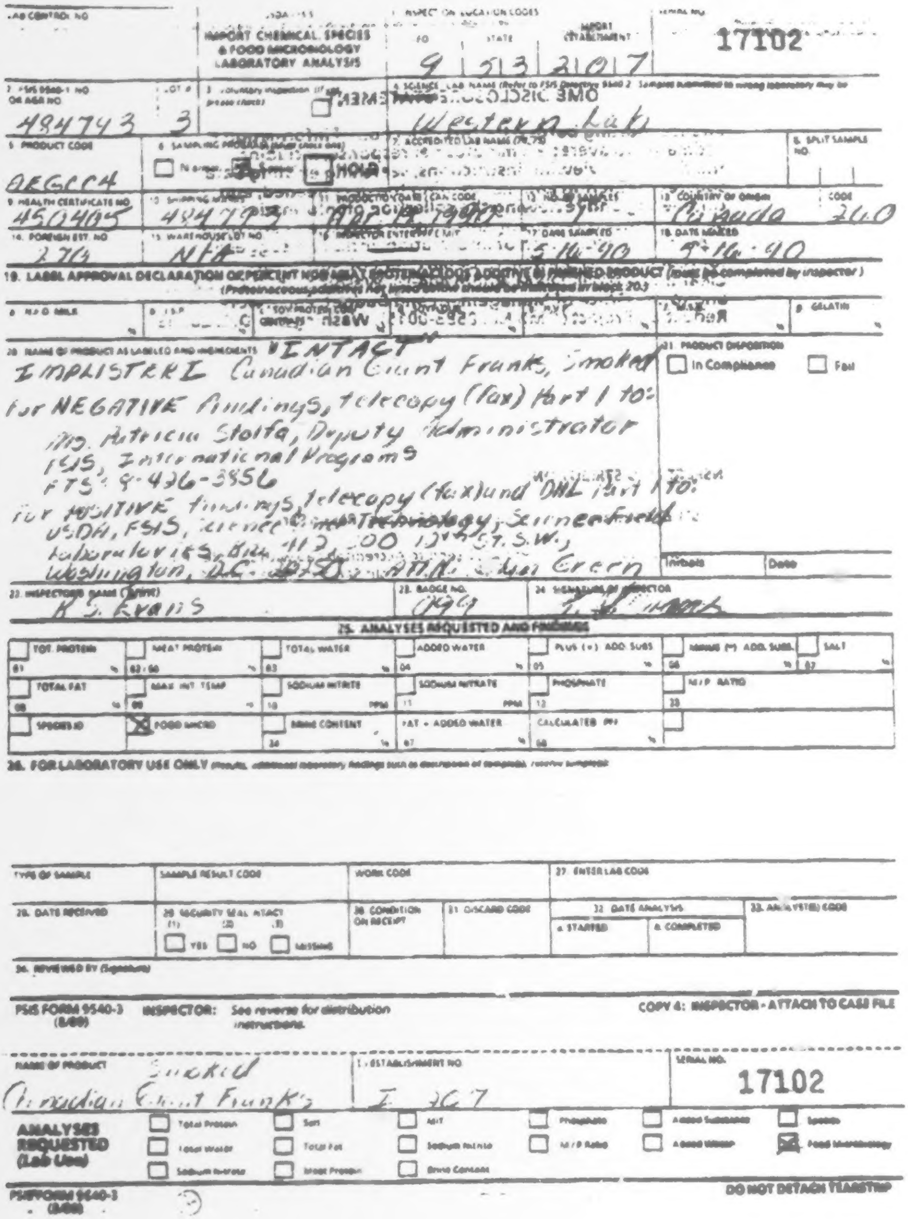
Prepared by: Dr. 1 [illegible]. Feltmate
Agri-Food Safety Division
Food Inspection Directorate
Room 506, Halldon House
995-5433 (Ext. 4666)
May 29, 1990

ATTACHMENT C

CANADA EST. 270 (FLETCHER'S)
LISTERIA VIOLATION

Date of lab findings	May 8, 1990
Date IID notified	May 8, 1990
Date Emergency Programs notified	May 8, 1990
No product left from Lot 2	May 15, 1990
Followup sample taken from Lot 3 (Results negative)	May 15, 1990

This lot consisted of
20 cartons, each carton
having 10 pounds of loose
franks



LAB CONTROL NO

USDA - FSIS
IMPORT CHEMICAL, SPECIES & FOOD MICROBIOLOGY LABORATORY ANALYSIS

1. INSPECTION LOCATION CODES
FO: 9 | STATE: 53 | IMPORT ESTABLISHMENT: 2107

SERIAL NO. 17102

2. FSIS 9540-1 NO OR AGR NO: 484743

LOT #: 3

3. Voluntary inspection (If yes, please check) ☐

4. SCIENCE LAB NAME (Refer to FSIS Directive 9840.2. Samples submitted to wrong laboratory may be ...): Western Lab

5. PRODUCT CODE: OEGCC4

6. SAMPLING PROGRAM (check one): ☐ Normal ☐ [illegible] ☐ HOLD

7. ACCREDITED LAB NAME

8. SPLIT SAMPLE NO.

9. HEALTH CERTIFICATE NO: 450405

10. SHIPPING MARKS: 484793

11. PRODUCTION DATE / CAN CODE: Apr 18 1990

12. NO. OF SAMPLES: 1

13. COUNTRY OF ORIGIN: Canada

CODE: 240

14. FOREIGN EST. NO: 270

15. WAREHOUSE LOT NO: N/A

16. INSPECTOR ENTERPRISE UNIT

17. DATE SAMPLED: 5-16-90

18. DATE MAILED: 5-16-90

19. LABEL APPROVAL DECLARATION OF PERCENT NON MEAT PROTEINACEOUS ADDITIVE IN FINISHED PRODUCT (must be completed by inspector)
(Proteinaceous additives not listed below should be identified in block 20.)

a. N.F.D. MILK % | b. I.S.P. % | c. SOY PROTEIN CONCENTRATE % | d. SOY FLOUR % | e. H.V.P. % | f. M.S.F. % | g. GELATIN %

20. NAME OF PRODUCT AS LABELED AND INGREDIENTS *INTACT
IMPLISTERRI Canadian Giant Franks, Smoked
for NEGATIVE findings, telecopy (fax) Part 1 to:
Ms. Patricia Stolfa, Deputy Administrator
FSIS, International Programs
FTS: 8-436-3856
for POSITIVE findings, telecopy (fax) and DHL Part 1 to:
USDA, FSIS, Science & Technology, Scientific Laboratories, Rm. 413, 300 12th St. S.W.,
Washington, D.C. 20250 ATTN: [illegible] Green

21. PRODUCT DISPOSITION
☐ In Compliance ☐ Fail

Initials | Date

22. INSPECTOR'S NAME (Print): K. S. Evans

23. BADGE NO.: 0999

24. SIGNATURE OF INSPECTOR

25. ANALYSES REQUESTED AND FINDINGS

☐ TOT. PROTEIN 01 %	☐ MEAT PROTEIN 02/50 %	☐ TOTAL WATER 03 %	☐ ADDED WATER 04 %	☐ PLUS (+) ADD. SUBS. 05 %	☐ MINUS (-) ADD. SUBS. 06 %	☐ SALT 07 %
☐ TOTAL FAT 08 %	☐ MAX INT. TEMP 09 °	☐ SODIUM NITRITE 10 PPM	☐ SODIUM NITRATE 11 PPM	☐ PHOSPHATE 12	☐ M/P RATIO 23	
☐ SPECIES ID	☒ FOOD MICRO	☐ BRINE CONTENT 34 %	FAT + ADDED WATER 67 %	CALCULATED PH 68 %	☐	

26. FOR LABORATORY USE ONLY (Results, additional laboratory findings such as description of samples, review samples)

TYPE OF SAMPLE | SAMPLE RESULT CODE | WORK CODE | 27. ENTER LAB CODE

28. DATE RECEIVED

29. SECURITY SEAL INTACT (1) ☐ YES (2) ☐ NO (3) ☐ MISSING

30. CONDITION ON RECEIPT

31. DISCARD CODE

32. DATE ANALYSIS a. STARTED b. COMPLETED

33. ANALYST(S) CODE

34. REVIEWED BY (Signature)

FSIS FORM 9540-3 (8/89)

INSPECTOR: See reverse for distribution instructions.

COPY 4: INSPECTOR - ATTACH TO CASE FILE

NAME OF PRODUCT: Smoked Canadian Giant Franks

1. ESTABLISHMENT NO: I 207

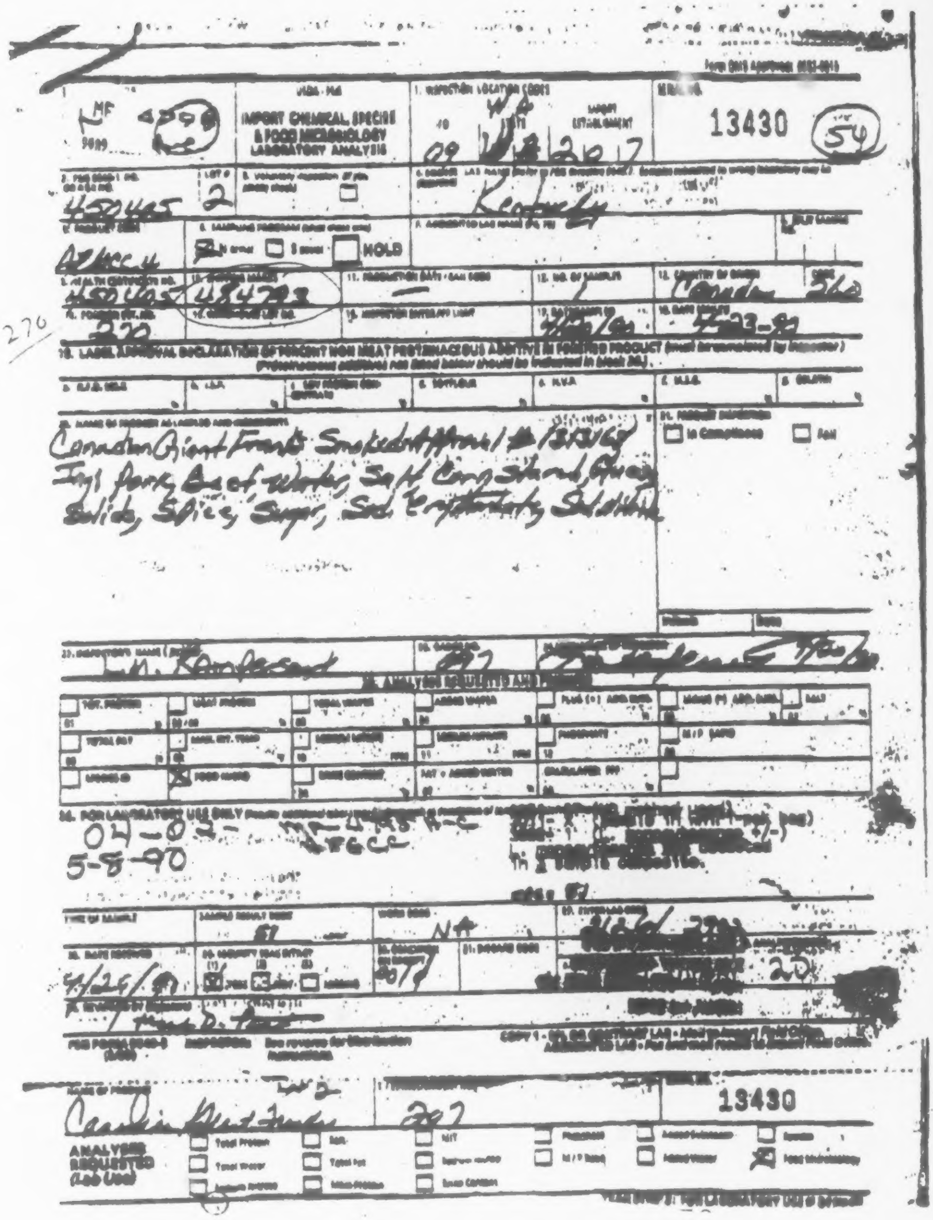
SERIAL NO. 17102

ANALYSES REQUESTED (Lab Use)

☐ Total Protein
☐ Total Water
☐ Sodium Nitrate
☐ Salt
☐ Total Fat
☐ Meat Protein
☐ MIT
☐ Sodium Nitrite
☐ Brine Content
☐ Phosphate
☐ M/P Ratio
☐ Added Substance
☐ Added Water
☐ Species
☒ Food Microbiology

FSIS FORM 9540-3 (8/89)

DO NOT DETACH TEARSTRIP



USDA - FSIS

IMPORT CHEMICAL, SPECIES & FOOD MICROBIOLOGY LABORATORY ANALYSIS

MF 4[illegible]

1. INSPECTION LOCATION CODES WP 09 [illegible] 2017

SERIAL NO. 13430 (54)

450U45

LOT 2

Kentucky

☒ [illegible] ☐ [illegible] ☐ HOLD

484793

Canada 560

270

4-23-90

☐ In Compliance ☐ Fail

Canadian Giant Franks Smoked [illegible] / # 1313[illegible]
Ing: Pork, Beef, Water, Salt, Corn Syrup, [illegible] Solids, Spice, Sugar, Sod. Erythorbate, Sod. Nitrite

W. Kampersand

207

☒ FOOD MICRO

04-02-
5-8-90

In 2 sample composite.

NA

4/26/90

25

FSIS FORM

COPY 1

Canadian Giant Franks

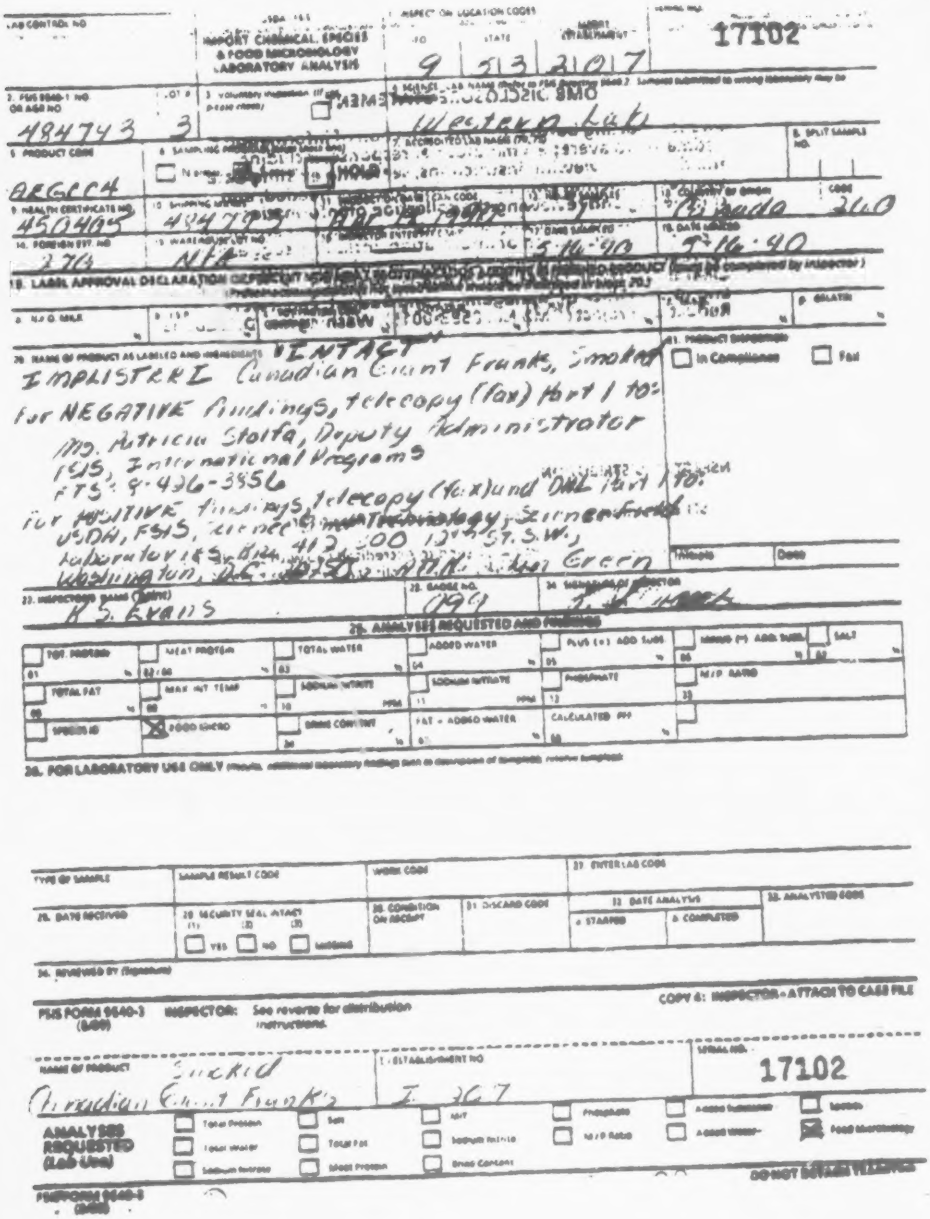
Lot 2

207

13430

ANALYSES REQUESTED (Lab Use)

☐ Total Protein ☐ Salt ☐ NIT ☐ Phosphate ☐ Added Substance ☐ Species
☐ Total Water ☐ Total Fat ☐ [illegible] ☐ M/P Ratio ☐ Added Water ☒ Food Microbiology
☐ [illegible] ☐ Meat Protein ☐ Bone Content



LAB CONTROL NO

USDA FSIS
IMPORT CHEMICAL, SPECIES & FOOD MICROBIOLOGY LABORATORY ANALYSIS

1. INSPECTION LOCATION CODES
RO: 9
STATE: 53
ESTABLISHMENT: 2017

SERIAL NO. 17102

2. FSIS 9540-1 NO OR AGR NO: 484743
LOT #: 3

3. Voluntary inspection ☐

4. [illegible] LAB NAME: Western Lab

5. PRODUCT CODE: ARGCC4

6. SAMPLING ☐ Normal ☐ HOLD

7. ACCREDITED LAB NAME

8. SPLIT SAMPLE NO.

9. HEALTH CERTIFICATE NO: 450405

10. SHIPPING MARKS: 484795

11. PRODUCTION DATE / CAN CODE: APR 12 1990

12. NO. OF SAMPLES

13. COUNTRY OF ORIGIN: Canada
CODE: 240

14. FOREIGN EST. NO: 270

15. WAREHOUSE LOT NO: N/A

16. INSPECTION ENTRY DATE

17. DATE SAMPLED: 5-16-90

18. DATE MAILED: 5-16-90

19. LABEL APPROVAL DECLARATION

20. NAME OF PRODUCT AS LABELED AND INGREDIENTS: INTACT Canadian Giant Franks, Smoked
IMPLISTERI
For NEGATIVE findings, telecopy (fax) Part 1 to:
Ms. Patricia Stolfa, Deputy Administrator
FSIS, International Programs
FTS: 8-436-3856
For POSITIVE findings, telecopy (fax) and DHL Part 1 to:
USDA, FSIS, Science & Technology, Science Field Laboratories, Rm. 412, 300 12th St. S.W.,
Washington, D.C. 20250 ATTN: [illegible] Green

21. PRODUCT DISPOSITION ☐ In Compliance ☐ Fail

Initials / Date

22. INSPECTOR'S NAME (Print): R. S. Evans

23. BADGE NO.: 094

24. SIGNATURE OF INSPECTOR

25. ANALYSES REQUESTED AND FINDINGS

☐ TOT. PROTEIN 01 %	☐ MEAT PROTEIN 02/06 %	☐ TOTAL WATER 03 %	☐ ADDED WATER 04 %	☐ PLUS (+) ADD SUBS 05 %	☐ MINUS (-) ADD SUBS 06 %	☐ SALT 07 %
☐ TOTAL FAT 08 %	☐ MAX INT TEMP 09	☐ SODIUM NITRITE 10 PPM	☐ SODIUM NITRATE 11 PPM	☐ PHOSPHATE 12	☐ M/P RATIO 13	
☐ SPECIES ID	☒ FOOD MICRO	☐ BRINE CONTENT 20 %	FAT + ADDED WATER 67 %	CALCULATED PFF 68 %	☐	

26. FOR LABORATORY USE ONLY

TYPE OF SAMPLE	SAMPLE RESULT CODE	WORK CODE	27. ENTER LAB CODE

28. DATE RECEIVED	29. SECURITY SEAL INTACT (1) ☐ YES (2) ☐ NO (3) ☐ MISSING	30. CONDITION ON RECEIPT	31. DISCARD CODE	32. DATE ANALYSIS a. STARTED	b. COMPLETED	33. ANALYSTS CODE

34. REVIEWED BY (Signature)

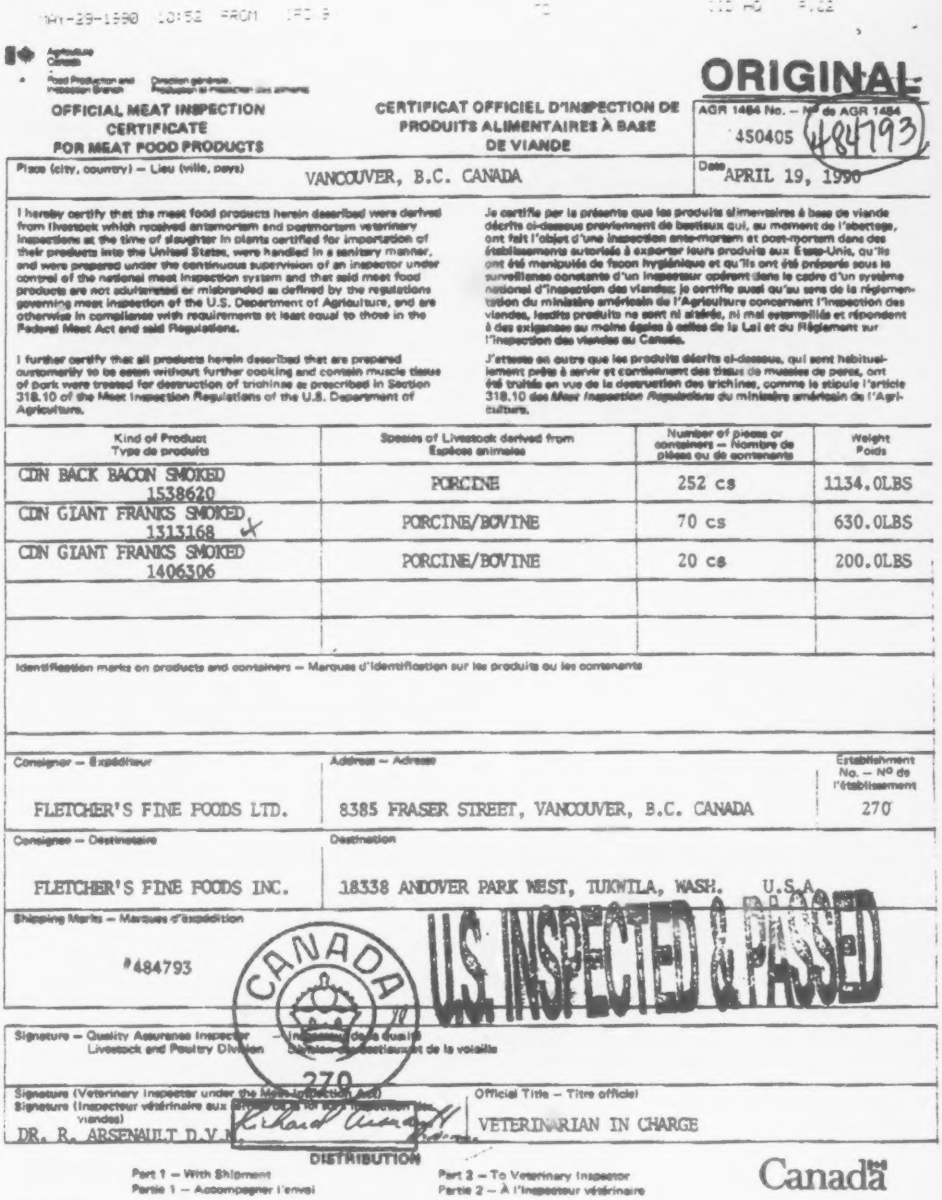
FSIS FORM 9540-3 (5/89)
INSPECTOR: See reverse for distribution instructions.
COPY 4: INSPECTOR - ATTACH TO CASE FILE

NAME OF PRODUCT: Smoked Canadian Giant Franks
1. ESTABLISHMENT NO: I 267
SERIAL NO. 17102

ANALYSES REQUESTED (Lab Use)
☐ Total Protein ☐ Total Water ☐ Sodium Nitrate
☐ Salt ☐ Total Fat ☐ Meat Protein
☐ MIT ☐ Sodium Nitrite ☐ Brine Content
☐ Phosphate ☐ M/P Ratio
☐ Added Substance ☐ Added Water
☐ Species ☒ Food Microbiology

DO NOT DETACH THIS STUB

FSIS FORM 9540-3 (5/89)



MAY-29-1990 10:52 FROM IFD B TO IID HQ P.02

Agriculture Canada
Food Production and Inspection Branch — Direction générale, Production et inspection des aliments

ORIGINAL

OFFICIAL MEAT INSPECTION CERTIFICATE FOR MEAT FOOD PRODUCTS

CERTIFICAT OFFICIEL D'INSPECTION DE PRODUITS ALIMENTAIRES À BASE DE VIANDE

AGR 1464 No. — Nº de AGR 1464: 450405 484793

Place (city, country) — Lieu (ville, pays): VANCOUVER, B.C. CANADA

Date: APRIL 19, 1990

I hereby certify that the meat food products herein described were derived from livestock which received antemortem and postmortem veterinary inspections at the time of slaughter in plants certified for importation of their products into the United States, were handled in a sanitary manner, and were prepared under the continuous supervision of an inspector under control of the national meat inspection system and that said meat food products are not adulterated or misbranded as defined by the regulations governing meat inspection of the U.S. Department of Agriculture, and are otherwise in compliance with requirements at least equal to those in the Federal Meat Act and said Regulations.

I further certify that all products herein described that are prepared customarily to be eaten without further cooking and contain muscle tissue of pork were treated for destruction of trichinae as prescribed in Section 318.10 of the Meat Inspection Regulations of the U.S. Department of Agriculture.

Je certifie par la présente que les produits alimentaires à base de viande décrits ci-dessus proviennent de bestiaux qui, au moment de l'abattage, ont fait l'objet d'une inspection ante-mortem et post-mortem dans des établissements autorisés à exporter leurs produits aux États-Unis, qu'ils ont été manipulés de façon hygiénique et qu'ils ont été préparés sous la surveillance constante d'un inspecteur opérant dans le cadre d'un système national d'inspection des viandes; je certifie aussi qu'au sens de la réglementation du ministère américain de l'Agriculture concernant l'inspection des viandes, lesdits produits ne sont ni altérés, ni mal estampillés et répondent à des exigences au moins égales à celles de la Loi et du Règlement sur l'inspection des viandes au Canada.

J'atteste en outre que les produits décrits ci-dessus, qui sont habituellement prêts à servir et contiennent des tissus de muscles de porcs, ont été traités en vue de la destruction des trichines, comme le stipule l'article 318.10 des *Meat Inspection Regulations* du ministère américain de l'Agriculture.

Kind of Product Type de produits	Species of Livestock derived from Espèces animales	Number of pieces or containers — Nombre de pièces ou de contenants	Weight Poids
CDN BACK BACON SMOKED 1538620	PORCINE	252 cs	1134.0LBS
CDN GIANT FRANKS SMOKED 1313168 ✓	PORCINE/BOVINE	70 cs	630.0LBS
CDN GIANT FRANKS SMOKED 1406306	PORCINE/BOVINE	20 cs	200.0LBS

Identification marks on products and containers — Marques d'identification sur les produits ou les contenants

Consignor — Expéditeur: FLETCHER'S FINE FOODS LTD.
Address — Adresse: 8385 FRASER STREET, VANCOUVER, B.C. CANADA
Establishment No. — Nº de l'établissement: 270

Consignee — Destinataire: FLETCHER'S FINE FOODS INC.
Destination: 18338 ANDOVER PARK WEST, TUKWILA, WASH. U.S.A.

Shipping Marks — Marques d'expédition: #484793

270

U.S. INSPECTED & PASSED

Signature — Quality Assurance Inspector — Inspecteur de la qualité
Livestock and Poultry Division — Division des bestiaux et de la volaille

Signature (Veterinary Inspector under the Meat Inspection Act)
Signature (Inspecteur vétérinaire aux termes de la loi sur l'inspection des viandes)
Richard Arsenault
DR. R. ARSENAULT D.V.M.

Official Title — Titre officiel: VETERINARIAN IN CHARGE

DISTRIBUTION

Part 1 — With Shipment
Partie 1 — Accompagner l'envoi

Part 2 — To Veterinary Inspector
Partie 2 — À l'inspecteur vétérinaire

Canada

AGR 1465 (81/10)

INITIAL ENTRY FORM M410

DOCUMENT NUMBER: 484793 IFO: 9 STATE: 53 L_HOUSE: 207

COUNTRY CODE: 260 ESTAB: 0270 CUSTOMS ENTRY NUMBER: 000000000000

LOT NUMBER	PRODUCT CODE/ LABEL #	PIECES (P) CARTONS (K) CONTAINERS (C) SUB-LOTS (L)	NUMBER OF P, K C OR L	NUMBER OF CANS PER CARTON	NET WEIGHT	MAKE ASSIGNMENT
1	PPORK	L	000002	001	0004405	X
2	FPORK	L	000010	001	0024056	X

PRINTING ON

Amended

INSPECTION ASSIGNMENT FOR CANADA

AGR No. 484793

SUB-LOT ① ② ③

FO 40 9

NUMBER OF RANDOM NUMBERS

RANGE From: To:

Generic Product Code PPORK

LEVEL OF INSPECTION

RANDOM NUMBERS

"THIS PRODUCT MUST PROCEED TO IMPORT ESTABLISHMENT IN U.S."

for Sublots ① ② ③

USDA-FSIS Employee's Signature Bea Bennett

Date 4-19-90

(For Non-FAX Use)

CANADIAN HEALTH CERTIFICATE

EXPORT STAMP

Canadian Inspector's Signature

Telephone #

Date

Pallet count	Range of Cartons on Pallet	Random Number (converted)	Pallet count	Range of Cartons on Pallet	Random Number (converted)
1.			16.		
2.			17.		
3.			18.		
4.			19.		
5.			20.		
6.			21.		
7.			22.		
8.			23.		
9.			24.		
10.			25.		
11.			26.		
12.			27.		
13.			28.		
14.			29.		
15.			30.		

Modified FSIS Form 9510-2 (01/89)

USDA-F

APRIL19

⊗

INITIAL ENTRY WORKSHEET FOR CANADA

Amended

Health Certificate AGR. No. 404793	U.S. Import Est. No. I-207	U.S. (City) Point of Entry BLAINE, WASH.

Canadian Est. No. 270	Canadian Inspector's Name Brian Wonnacott	Telephone No. (604) 321-6681	Fax No. 604-321-5624

Generic Product Code (Only One per Sheet) : P - PORK

Sub-Lot Number	Specific Name of Product	P-1 side 2 qtrs K-Pkgs. C-Cans	Number of P,K,C (1 combo -18K)	Net Weight
1 *	PORK BACK BACON P30400 1538620	K	250 CS	3575-0 LBS
2 **	CDN GIANT FRANKS AEGCO4 1311368	K	70 CS	630-0 LBS
3	CDN GIANT FRANKS AEGCC4 1406306	K	20 CS.	200.0 LBS
		K		
	* Lab-Protein Fat Free (Intensified)			
	** Listeria Sampling	K		
		K		
		K		
		K		
*		* Net Weight Total -	4405-0 LBS	

FSIS Form 9510-1 (01/89)

CANADA EST. 35 (SCHNEIDER'S)
LISTERIA VIOLATION

Date of lab findings	June 20, 1990
Date IID notified	June 20, 1990
Date Emergency Programs notified	June 20, 1990
Date product located	June 20, 1990 - 10 cartons, 120 pounds. Other product from that production date was also produced and sold in the U.S.

Date of disposition of product

A first class recall was initiated on June 22, 1990, but was later expanded on June 26, 1990, to include additional states.

9,509 pounds of product was located and denatured on July 31, 1990.

PRELIMINARY
EMERGENCY PROGRAMS STAFF
NOTIFICATION
*****

DATE : June 22, 1990 **EP NUMBER:** 0025

TIME : NA

EST. NO. : 35, Canada

6/22/90

EST. NAME : J. M. Schneider Inc.

EST. ADDRESS: 321 Cortland Ave. East, Kitchener, Ontario N2G 2W1

PERSON(S) : Doug Palo, IID

NATURE OF INCIDENT:

A monitoring sample (intact) of Schneiders Franks, 16 oz, Best Before JUL 03, was positive for Listeria monocytogenes.

BACKGROUND:

Information from Schneiders in Canada, is that 1800 cartons of product was produced with the JUL 03 "sell by" date, 1600 of which were exported to the U.S.

ACTION:

Class I recall with public notification.

Samples requested: **In-plant** - none
Compliance - none

Plant Management Notified: by IP 6/25/90

Date:
McDougall, MPIO
Callstrom, Acting ADA
Mina, IMP
Skinner, FPD
Johnston, MD
Parham, EPID
Clerkin, CP
Manis, IID
Whitney, SO
NERO, NCRO

EP-0025

we need to contact J. M. Schneider Inc. and get them to agree to have the product at Holly, NY, destroyed under FSIS supervision.

Mike Grasso advised eem on 7/24/90 that 9,000 pounds (?) at the Holly warehouse are being held for disposition. I had spoken weeks ago with Ian Kirk, GOC, and we discussed the idea of the product returning to Canada under company seal for destruction in Canada.

It would be better control on our part to have such product destroyed under our supervision and not return it to the country of origin, as Glenn did recently with the mortadella.

Nash is willing to have his people supervise the destruction, but we need a voluntary consent order agreed to by the owner of the product.

CONTACTS:

Holly Cold Storage	Tel: 716-638-6393
Dr. Ian Kirk GOC	Tel:9-1-613-995-5433 FAX:9-1-613-998-0958

Need J. M. Schneider's telephone number. Give them our fax so they can send a[illegible]n letter OKing the destruction. May have to work this out through Ian Kirk.

eem
7/24/90 23 ?
4:31 pm

8/1/90
Donna Jackson IID, 9509 lbs of product
denatured 7/31/90.

NEWS

United States
Department of
Agriculture

Office of
Public Affairs

Office of Press and Media Relations
News Division, Room 404-A
Washington, D.C.20250

Jim Greene (202) 382-0314
Arthur Whitmore (202) 447-4026

SCHNEIDERS EXPANDS RECALL OF FRANKS NATIONWIDE

WASHINGTON, June 26--J.M. Schneider, Inc., of Ontario, Canada, is voluntarily expanding its recall of "Schneider's Franks" to include grocery markets nationwide. The franks may be contaminated with the bacterium *Listeria monocytogenes*.

The franks are sold in 1-pound plastic packages. The words "Canada 35" appear inside the inspection seal on the label. Approximately 22,000 pounds of franks bearing the "Best before" date of "Jul 03" are being recalled.

The original recall of June 22 was confined only to unspecified states in "the Northeastern United States." However, further investigation revealed the franks were distributed in California, Connecticut, Massachusetts, New York, Pennsylvania, Michigan, Ohio, Maryland and Texas.

"Although no illnesses have been associated with *listeria*, several consumer complaints are being investigated," said Dr. Ronald J. Prucha, associate administrator of the U.S. Department of Agriculture's Food Safety and Inspection Service. "We urge consumers to return the suspect franks to the place of purchase," said Prucha. None of the company's other products are involved in the recall.

The problem was discovered during a routine USDA import reinspection in Buffalo, N.Y.

Consumption of food contaminated with Listeria monocytogenes can cause listeriosis, a rare but potentially serious disease. In general, healthy people are believed to be at little risk from listeriosis; most

-more-

832-90

0713

vulnerable are those with weakened immune systems--infants, the elderly, and the chronically ill. Listeriosis in pregnant women can cause miscarriage.

Symptoms of listeriosis in adults include the sudden onset of flu-like symptoms such as fever, chills, headache, backache, and sometimes abdominal pain and diarrhea. Symptoms in newborns include respiratory distress, refusal to drink, and vomiting.

Consumers with questions about the recall may phone the toll-free USDA Meat and Poultry Hotline at 1-800-535-4555. The hotline can be reached from 10 a.m. to 4 p.m. Eastern time Monday through Friday. At other times a recording with information about the recall will be provided. Callers in the Washington, D.C., metropolitan area should call 447-3333. Both phone numbers provide access to a telecommunications device for the deaf.

The Food Safety and Inspection Service ensures the safety of all meat and poultry products sold in interstate commerce -- including products from other countries. FSIS inspection also ensures product wholesomeness and accuracy of labeling information.

#

NEWS

United States
Department of
Agriculture

Office of
Public Affairs

Office of Press and Media Relations
News Division, Room 404-A
Washington, D.C.20250

Jim Greene (202) 382-0314
Edwin Moffett (202) 447-4026

SCHNEIDERS RECALLS FRANKS FROM NORTHEASTERN U.S.

WASHINGTON, June 22--J.M. Schneider, Inc., Ontario, Canada, is voluntarily recalling approximately 20,000 pounds of its "Schneider's Franks" distributed to retail grocery markets in the Northeastern United States because the franks may be contaminated with the bacterium, Listeria monocytogenes.

The franks are sold in one pound plastic packages. The words "Canada 35" appear inside the inspection seal on the label. All franks bearing the "Best before" date of "Jul 03" are being recalled.

"Although no illnesses have been reported, we urge consumers to return the suspect franks to the place of purchase," said Dr. Ronald J. Prucha, associate administrator of USDA's Food Safety and Inspection Service. None of the company's other products are involved in the recall. The problem was discovered during a routine USDA import re-inspection in Buffalo, N.Y.

Consumption of food contaminated with Listeria monocytogenes can cause listeriosis, a rare but potentially serious disease. In general, healthy people are believed to be at little risk from listeriosis; most vulnerable are those with weakened immune systems--infants, the elderly and the chronically ill. Listeriosis in pregnant women can cause miscarriage.

Symptoms of listeriosis in adults include the sudden onset of flu-like symptoms such as fever, chills, headache, backache and sometimes abdominal pain and diarrhea. Symptoms in newborns include respiratory distress, refusal to drink and vomiting.

Consumers with questions about the recall may phone the toll-free USDA Meat and Poultry Hotline at 1-800 535-4555. The hotline can be reached from 10 a.m. to 4 p.m. (Eastern Time) Monday through Friday. At other times a recording with information about the recall will be provided. Callers in the Washington, D.C. metropolitan area should call 447-3333. Both phone numbers provide access to a telecommunications device for the deaf.

FSIS inspects all meat and poultry sold in interstate commerce to ensure that it is safe, wholesome and accurately labeled.

#

813-90

0696

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

JUN 28 1990

SPECIAL DELIVERY-CERTIFIED
RETURN RECEIPT REQUESTED

J. M. Schneider Inc.
321 Courtland Avenue East
Kitchener, Ontario N2G 2W1

Dear Sirs:

This is in regard to your voluntary recall of Schneiders Franks exported to the United States with the "Best before" of "JUL 03", because of contamination with Listeria monocytogenes, a bacterial organism that can produce a serious disease.

On May 29, 1990, a monitoring sample of Schneiders Franks was collected by the Import Inspection Division, Food Safety and Inspection Service (FSIS), U. S. Department of Agriculture. This sample was subsequently found to contain Listeria monocytogenes. On June 6, 1990, another monitoring sample was collected and this also was found to be contaminated with Listeria monocytogenes. Both samples carried the same "Best before" of "JUL 03". On June 22, 1990, FSIS received information that you were recalling all product in question.

On Friday, June 22, 1990, the Administrator of FSIS, concurred with our recommendation for a Class I recall, which is appropriate because of the probable serious, adverse health consequences involved. That same day a press release was issued identifying the product and the problem, stating that the product was distributed in the northeastern U.S. We later received more precise information on the distribution and issued a second press release stating that the product was distributed in California, Connecticut, Massachusetts, New York, Pennsylvania, Michigan, Ohio, Maryland and Texas. A copy of both press releases are enclosed.

Mr. Dick Nash, Compliance Specialist, Washington, D. C., is the FSIS headquarters recall coordinator for this case. He is responsible for directing the FSIS compliance officers to contact the U. S. distributors of the product with instructions to return the product, to the extent possible, to one central location under FSIS jurisdiction. When all product available has been returned, it will be destroyed for human food under FSIS supervision. Mr. Nash will also be directing the FSIS compliance officers to complete effectiveness checks to the retail level. At the conclusion of the recall Mr. Nash will receive an accounting from the consignees as to the volume of the JUL 03 code recalled and destroyed. This information will be furnished to our Agency's Import Inspection Division.

For your information we are furnishing you with a copy of our recall directive so that you may better understand the basis for our actions, and a set of examples of the kinds of notification a recalling firm sends to their consignees. In these examples of notifications, the firm describes the nature of the defect so as to accurately convey the sense of urgency in the action the firm is requesting.

Your prompt action in this matter is appreciated.

Sincerely,

/s/ E.E. Montgomery

Earl E. Montgomery
Director, Emergency Programs Staff
Inspection Operations

Enclosures

cc:
K. McDougall, IO
R. Callstrom, IMP
M. Mina, IMP
P. Clerkin, CP
C. Nash, CP
M. Manis, IID
L. Skinner, FPD
Regional Offices

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

FACSIMILE MESSAGE

FROM:
MARK MANIS, DIRECTOR
USDA/FSIS IMPORT INSPECTION DIVISION
INTERNATIONAL PROGRAMS
ROOM 0114-SOUTH (202) 447-2952
FAX: FTS OR (202) 472-3588

TO: [redacted] [redacted] Dr. Montgomery
E.P.S.

NO. OF PAGES TRANSMITTED 4
(INCLUDING COVER SHEET)

DATE 6/20/90

SUBJECT: FYI as requested

06/20/1990 14:57 IID HDQRTS. FSIS/IP 202 472 3588 P.02
WASH. D.C. P.01
JUN-20-1990 16:16 FROM USDA-FSIS-IMPORT-IFO-1 TO

Peter J Schmitt
No Address
Could not
Contact
Not under Inspection

IMPORT INSPECTION DIVISION

INITAL RESIDUE AND LISTERIA VIOLATION TRACE BACK

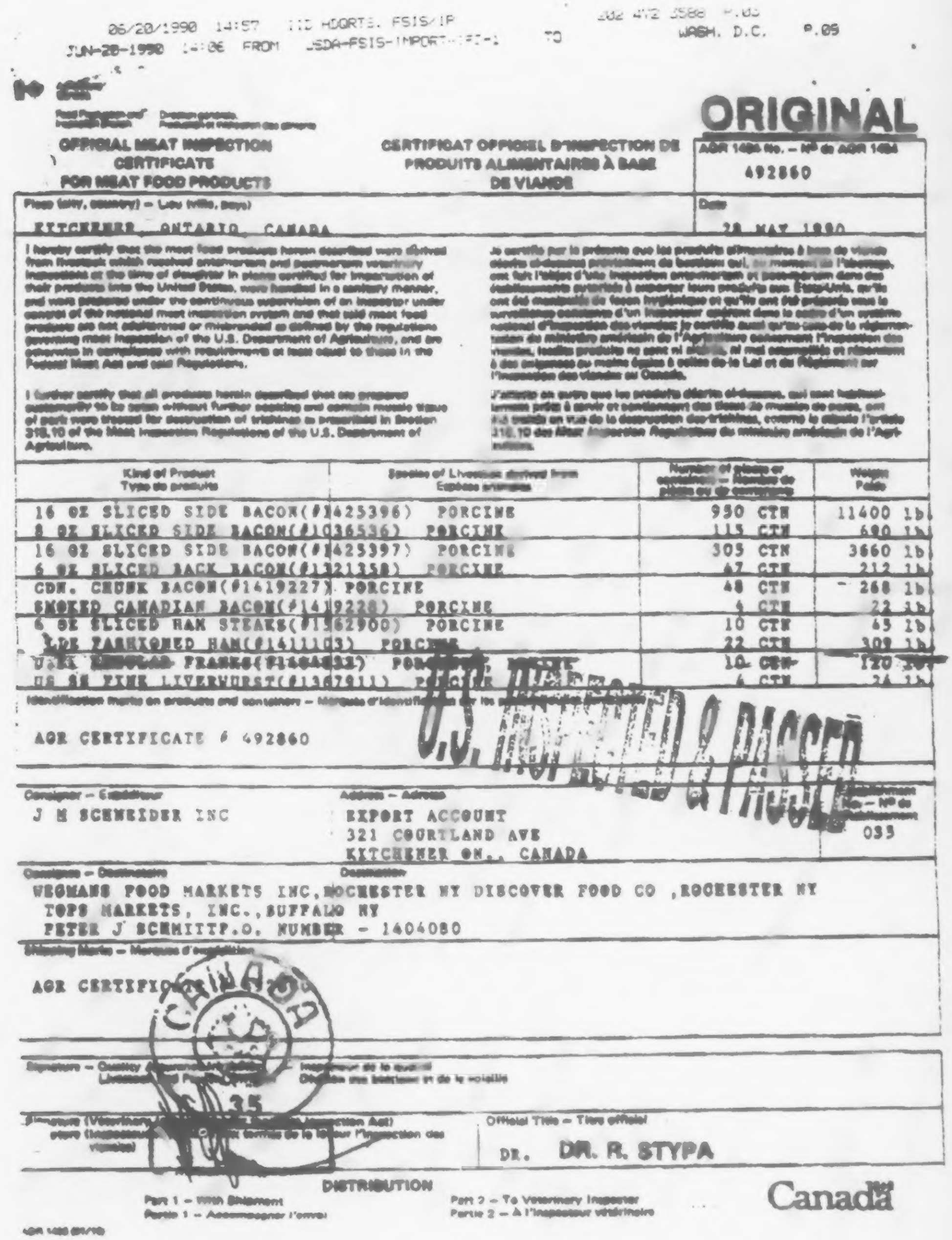
VIOLATIVE ~~COMPOUND & AMOUNT~~ Listeria IFO# 1
COUNTRY Canada AGR # 492860-1 DATE 6/20/90
EST.# 35 IFO CONTACT Bob Fasulo
PRODUCT NAME Schneiders Franks *SEND COPY OF 95~~40~~-1 & HEALTH CERT.*
492860

PRESENT LOCATION OF PRODUCT:
CO. NAME Wegmans Food Market Inc. CARTONS Total 10
ADDRESS Rochester NY WEIGHT 120
NAME OF MANAGER ETC. Ilse Frasher
PHONE#
Non on Hand
Never Received
this order

PRESENT LOCATION OF PRODUCT:
CO. NAME Discover Foods Co CARTONS 10
ADDRESS Rochester NY WEIGHT 120
NAME OF MANAGER ETC.
PHONE#
Could not
contact
Not under Inspection

PRESENT LOCATION OF PRODUCT:
CO. NAME Tops Markets Inc CARTONS 10
ADDRESS Buffalo NY WEIGHT 120
NAME OF MANAGER ETC.
PHONE#
Could not contact
Not under Inspection

IID STAFF PERSON D. Palo
E.P.S. STAFF PERSON Dr. Montgomery DATE NOTIFIED 6/20/90



06/20/1990 14:57 IID HDQRTS. FSIS/IP 202 472 3588 P.05

JUN-20-1990 14:06 FROM USDA-FSIS-IMPORT-IPI-1 TO WASH. D.C. P.05

ORIGINAL

OFFICIAL MEAT INSPECTION CERTIFICATE FOR MEAT FOOD PRODUCTS

CERTIFICAT OFFICIEL D'INSPECTION DE PRODUITS ALIMENTAIRES À BASE DE VIANDE

AGR 1454 No. – Nº de AGR 1454: 492860

Place (city, country) – Lieu (ville, pays): KITCHENER, ONTARIO, CANADA

Date: 28 MAY 1990

I hereby certify that the meat food products herein described were derived from livestock which received antemortem and postmortem veterinary inspections at the time of slaughter in plants certified for importation of their products into the United States, were handled in a sanitary manner, and were prepared under the continuous supervision of an inspector under control of the national meat inspection system and that said meat food products are not adulterated or misbranded as defined by the regulations governing meat inspection of the U.S. Department of Agriculture, and are otherwise in compliance with requirements at least equal to those in the Federal Meat Act and said Regulations.

I further certify that all products herein described that are prepared customarily to be eaten without further cooking and contain muscle tissue of pork were treated for destruction of trichinae as prescribed in Section 318.10 of the Meat Inspection Regulations of the U.S. Department of Agriculture.

Kind of Product Type de produits	Species of Livestock derived from Espèces animales	Number of pieces or containers – Nombre de pièces ou de contenants	Weight Poids
16 OZ SLICED SIDE BACON(#1425396)	PORCINE	950 CTN	11400 lb
8 OZ SLICED SIDE BACON(#1036536)	PORCINE	115 CTN	690 lb
16 OZ SLICED SIDE BACON(#1425397)	PORCINE	305 CTN	3660 lb
6 OZ SLICED BACK BACON(#1321358)	PORCINE	47 CTN	212 lb
CDN. CHUNK BACON(#1419227)	PORCINE	48 CTN	268 lb
SMOKED CANADIAN BACON(#1419228)	PORCINE	4 CTN	22 lb
6 OZ SLICED HAM STEAKS(#1562900)	PORCINE	10 CTN	65 lb
OLD FASHIONED HAM(#1411103)	PORCINE	22 CTN	309 lb
U.S.1 [illegible] FRANKS([illegible])	[illegible]	10 CTN	120 lb
US #1 FINE LIVERWURST(#1367911)	PORCINE	4 CTN	24 lb

U.S. INSPECTED & PASSED

Identification marks on products and containers – Marques d'identification sur les produits et contenants

AGR CERTIFICATE # 492860

Consignor – Expéditeur: J M SCHNEIDER INC

Address – Adresse:
EXPORT ACCOUNT
321 COURTLAND AVE
KITCHENER ON., CANADA

Establishment No. – Nº de l'établissement: 035

Consignee – Destinataire / Destination:
WEGMANS FOOD MARKETS INC, ROCHESTER NY DISCOVER FOOD CO ,ROCHESTER NY
TOPS MARKETS, INC., BUFFALO NY
PETER J SCHMITTP.O. NUMBER - 1404080

Shipping Marks – Marques d'expédition:

AGR CERTIFICATE

CANADA 35

Signature – Quality Assurance Inspector, Livestock and Poultry Division – Inspecteur de la qualité, Division des bestiaux et de la volaille

Signature (Veterinary Inspector, Meat Inspection Act)

Official Title – Titre officiel: DR. DR. R. STYPA

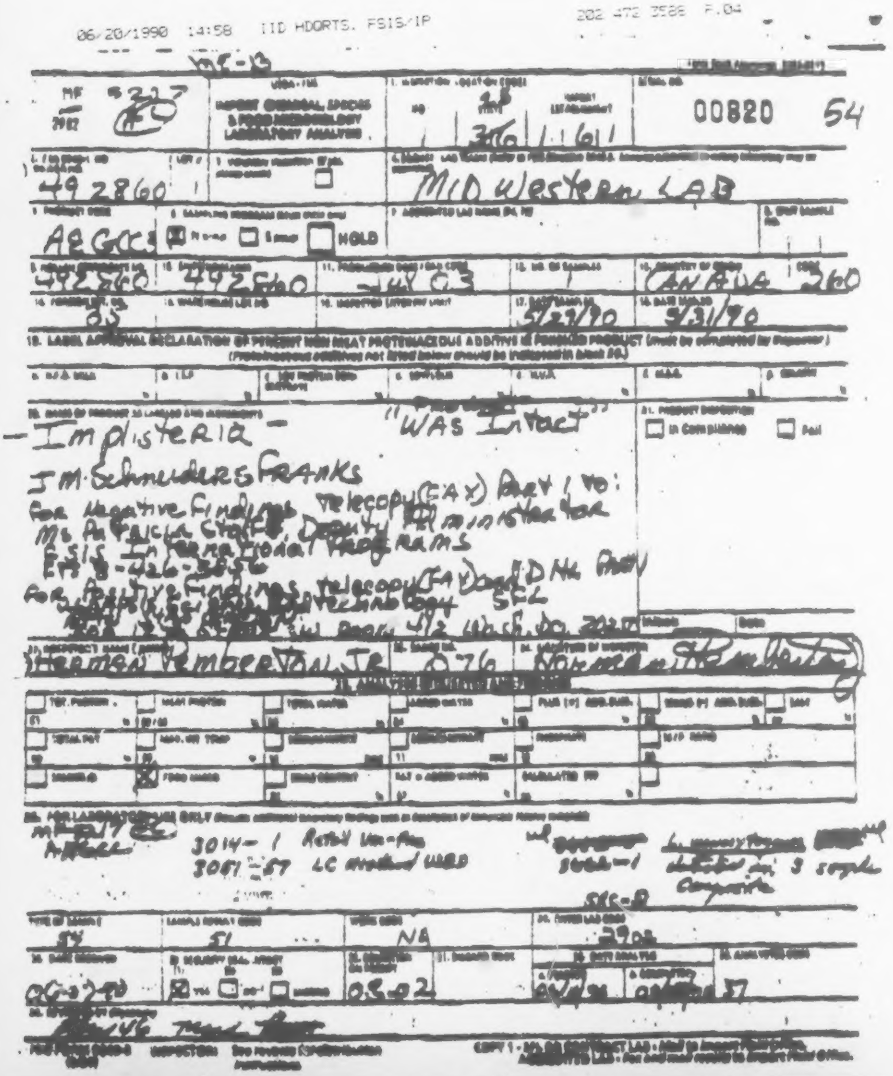
DISTRIBUTION

Part 1 – With Shipment
Partie 1 – Accompagner l'envoi

Part 2 – To Veterinary Inspector
Partie 2 – À l'inspecteur vétérinaire

Canada

AGR 1450 (81/10)



06/20/1990 14:58 IID HDQRTS. FSIS/IP 202 472 3588 P.04

MF 5227

00820 54

316 | 1 | 611

492860 | 1

MID WesteRn LAB

AEGCC3 ☒ HOLD

492860 | 492860 | JUY C3 | 1 | CANADA | 260

0.5 | 5/29/90 | 5/31/90

19. LABEL APPROVAL DECLARATION OF PERCENT NON MEAT PROTEINACEOUS ADDITIVE IN FINISHED PRODUCT

-Implisteria- "WAS Intact"

☐ In Compliance ☐ Fail

J.M. Schneiders Franks

For Negative Findings Telecopy (FAX) Part 1 to:

Ms Patricia Stolfa, Deputy Administrator

FSIS International Programs

For Positive Findings telecopy (FAX)

Herman Pemberton Jr. | 0-76

☒

3014-1 Retail Vac-Pac

3051-57 LC modified USDA

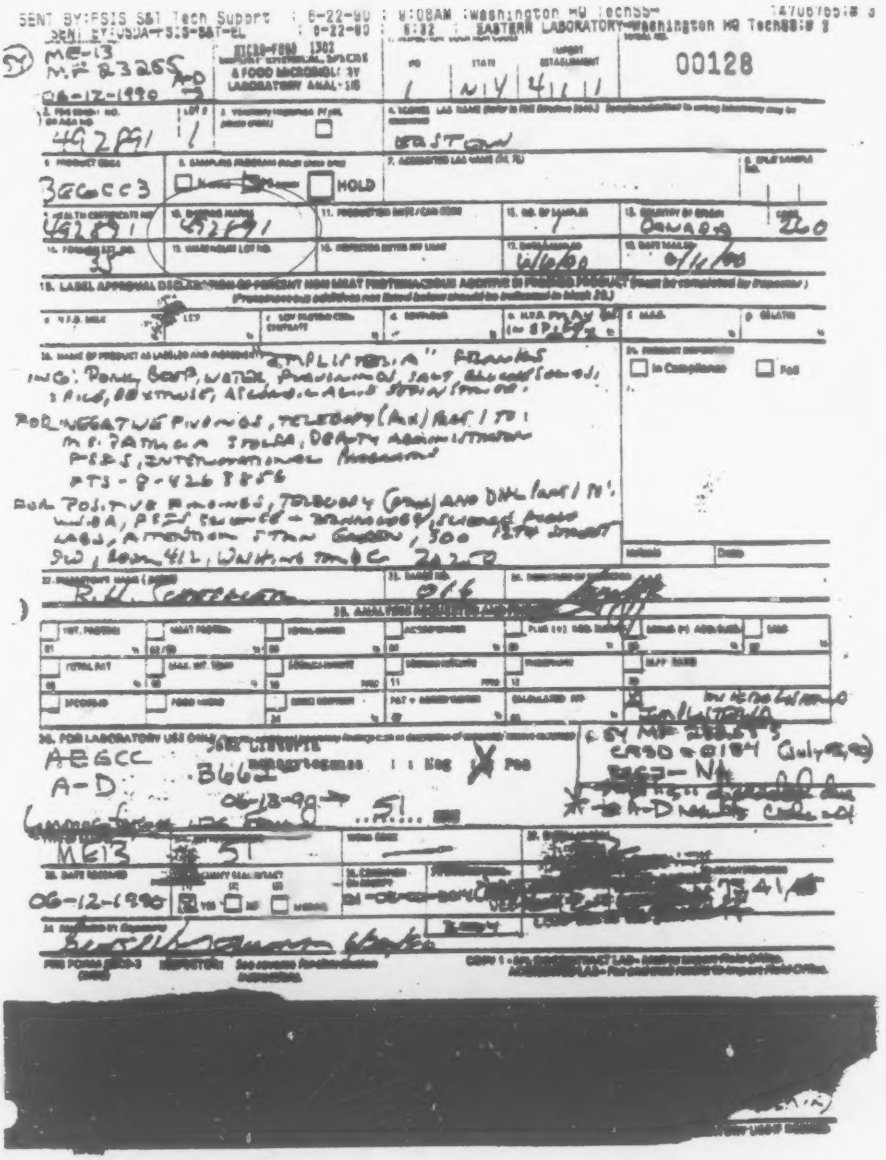
3066-1

detected in 3 sample Composite

SFC-B

54 | 51 | NA | 2902

06-07-90 ☒ ☐ ☐ | 05-02 | 37



SENT BY:FSIS S&T Tech Suport : 6-22-90 : 9:08AM :Washington HQ Tech55→ [illegible]
SENT BY:USDA-FSIS-S&T-EL : 6-22-90 : 6:32 : EASTERN LABORATORY→Washington HQ Tech55:# 2

(51) ME-13
M.F 83265
06-12-1990

MICRO-FORM 1302
& FOOD MICROBIOLOGY
LABORATORY ANAL-SIS

PO	STATE	IMPORT ESTABLISHMENT	00128
1	N.Y	4111	

492891 | 1 | EASTERN

3GGCC3 | ☐ [illegible] ☐ [illegible] ☐ HOLD

492891 | 492891 | 1 | Canada | 220

6/6/90 | 6/11/90

19. LABEL APPROVAL DECLARATION OF PERCENT NON MEAT [illegible] (Must be completed by [illegible])

"EMPLISTERIA" FRANKS
ING: PORK, BEEF, WATER, [illegible], SALT, [illegible], SPICE, DEXTROSE, [illegible] NITRITE.

FOR NEGATIVE FINDINGS, TELECOPY (FAX) PART 1 TO:
MS. PATRICIA STOLFA, DEPUTY ADMINISTRATOR
FSIS, INTERNATIONAL PROGRAMS
FTS - 8 - 426 8856

FOR POSITIVE FINDINGS, TELECOPY (FAX) AND DHL PART 1 TO:
USDA, FSIS SCIENCE - TECHNOLOGY, SCIENCE [illegible]
LABS, ATTENTION STAN GREEN, 300 12TH STREET
SW, ROOM 412, WASHINGTON DC 20250

☐ In Compliance ☐ Fail

R.H. [illegible] | 016

33. ANALYSES [illegible]

☒ [illegible] LISTERIA

36. FOR LABORATORY USE ONLY
AEGCC
A-D . . . B662 : : Neg ☒ Pos
06-13-90 → 51

L. 51 MF 83265
CRSD = 0184 (July [illegible] 90)
[illegible] — NA
* [illegible] A-D [illegible]

ME13 | 51

06-12-1990 | ☒ Yes ☐ No ☐ [illegible]

FSIS FORM [illegible] INSPECTOR: See reverse [illegible]

[redacted]

CANADA EST. 224 (SANTA MARIA FOODS)
LISTERIA VIOLATION

Date of lab findings	July 6, 1990
Date IID notified	July 6, 1990
Date Emergency Programs notified	July 6, 1990
Date product located	July 6, 1990
Date of disposition of product	July 18, 1990

Product was voluntarily destroyed at AA-1 Food Distribution 1405 Jeffery Drive, Addison, IL

EMERGENCY PROGRAMS STAFF
NOTIFICATION OF CASE CLOSURE

*****

EP CASE NO.: 0026

DATE CLOSED: July 23, 1990

7/23/90

EST. NUMBER: 224, Canada

EST. NAME : Santa Maria Foods Ltd., Rexdale, Ontario

CONTACT PERSON: Glenn L. Leslie, EPS

BASIS:

Product in question was voluntarily destroyed for human food purposes by the importer, AA-1 Food Distribution, 1405 Jeffery Drive, Addison, IL 60101 on July 18, 1990. The shipment consisted of 52 cases or Approximately 1530 pounds and was intact except for the piece sampled by IID.

BACKGROUND:

An intact monitoring sample of Mortadella from Establishment 224 was sampled for Listeria by the IID, and subsequently was found to be positive. Product had not been retained pending laboratory analysis, but according to importer product was not in commerce and had not been used.

PSIS UNITS INVOLVED:

Compliance
Inspection Management Program
Epidemiology
Foreign Programs
Import Inspection Division
IP, PDD
Microbiology
Scientific Operations
Northeastern Regional Office

7/23/90

ALL UNITS NOTIFIED OF CLOSURE.

SAMPLE RESERVE: Discard

PRELIMINARY
EMERGENCY PROGRAMS STAFF
NOTIFICATION
*****

DATE : July 6, 1990 **EP NUMBER:** 0026

TIME : 2:05

EST. NO. : 224, Canada

7/9/90

EST. NAME : Santa Maria Foods Ltd.

EST. ADDRESS: 353 Humberline Dr., Rexdale, Ontario

PERSON(S) : Doug Palo, IID

NATURE OF INCIDENT:

An intact monitoring sample of Mortadella from Establishment 224 was sampled for Listeria by the IID, and subsequently was found to be positive. Product had not been retained pending laboratory analysis, but according to importer product is not in commerce and has not been used.

ACTION:

1. Determine if product is in commerce.
2. Identify Product by Product and production codes.
3. Determine if other product of same code(s) was exported to U.S. at other times/customers.

Samples requested: NO

Plant Management Notified: Yes

JD 7/9/90

Date:
McDougall, MPIO
Callstrom, Acting ADA
Mina, IMP
Skinner, FPD
Johnston, MD
Parham, EPID
Clerkin, CP
Manis, IID
Whitney, SO
NERO

CHRONOLOGY: EP-0026

7/6/90
1:55
Stan Green, MD, called to inform EPS that there was another positive listeria from Canada, and also a species violation.

2:05
Doug Palo, IID, Listeria positive, and species violation. Product was imported by A-1 Food Distributors Inc, 1405 Jeffy Dr., Addison, IL. Contact Sal Ciccone (708) 495-9292.

Called Mr. Ciccone, he informed EPS that he has called his customers and all the product was accounted for (except for the one sampled). Further, all the product would be at his warehouse by this afternoon or by Monday. EPS imformed him to hold product until FSIS contacted him as to what will happen to the product.

2:30
Called the plant in Canada, Asked for Richard Hawley 416-675-1785, I don't know if I spoke to Richard but I was informed that the product in question is only sold to AA-1, who in turn sells it for further processing (used to make a meat stuffing). He asked if he would get the product back and I told him he probably would but I was not sure at this time.

7/9/90
Asked Doug Palo to ge production and distribution information through Agriculture Canada.

7/10/90
10:00
To Mr. Ciccone, EPS informed him that the product would have to be destroyed for human use, and that a compliance officer would be in touch with him to make arrangements for that. Mr. Ciccone asked for a letter stating that the product had to be destroyed.

1:50
To Richard Hawely, Santa Maria Foods Ltd., explained that product would not be going back to Canada but would be destroyed for human food here in the U.S. There was no objection.

7/11/90
2:25
Doug Palo, IID, The Canadian Meat Inspection Service reports that the 1530.20 lbs of product in question was the total production of that product for 6/15/90 (code=1690 - 169=6/15, 0=1990).

JULY 9, 1989, 4:00 PM

EP CASE 0026

REPORT FROM DALE BAGLEY:

ALL PRODUCT (MORTADELA) IS ACCOUNTED FOR AT A-1 FOOD INC, ADDISON, IL. TOTAL OF 52 BOXES.

PRODUCTION CODE ON THE BOX: 1690 (JULIAN DATE: 6/18/90)
INVOICE DATE: JUNE 22
BEST IF CONSUMED BEFORE SE 26 (MEANING SEPT 26 MAYBE)

NO OTHER PRODUCT AVAILABEL AT THE PLANT. NOT AWARE OF OTHER SHIPMENTS TO OTHER PLANTS.

PRODUCT AWAITS INSTRUCTION FOR DISPOSITION.
THE PRESENCE OF CO SHOOK THE PEOPLE IN THE PLANT AND THEY WILL NOT MESS WITH THE PRODUCT.

JUL 11 1990

Mr. Sal Ciccone
A-1 Food Distributors
1405 Jeffy Drive
Addison, IL 60101

SPECIAL DELIVERY-CERTIFIED
RETURN RECIEPT REQUESTED

Dear Mr. Ciccone:

This is in regard to your conversation of July 10, 1990, with our staff concerning the disposition of 1,530 pounds of Mortadella imported from Santa Maria Foods Limited, Rexdale, Ontario.

The product in question was imported and sampled on June 25, 1990, at Import Establishment I-265. Subsequently laboratory analysis revealed that the product was contaminated with Listeria Monocytogenes, a pathogenic bacteria.

Since the product is potentially dangerous to consumers, it must be destroyed for human purposes, and the destruction must be under the supervision of the Food Safety and Inspection Service (FSIS). A Compliance Officer from FSIS will be contacting you soon to make arrangements for the destruction of the product.

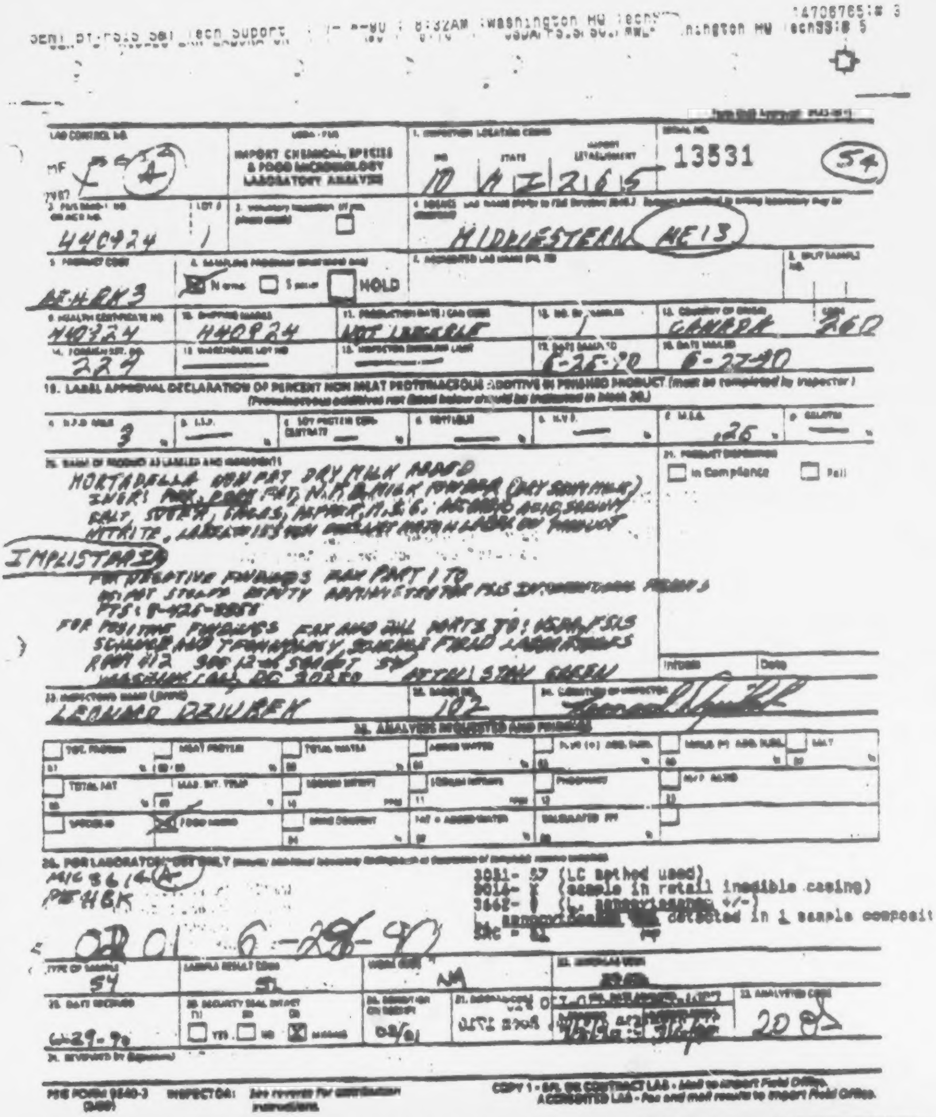
Thank you for your cooperation in this matter. If you have any questions feel free to call Emergency Programs Staff, our telephone number is (202) 447-3033.

Sincerely,

/s/ E.E. Montgomery

Earl Montgomery
Emergency Programs Staff
Inspection Operations
cc:
R. Callstrom, Acting ADA
M. Mina, IMP
M. Manis, IID
L. Skinner, FPD
R. Johnston, MD
P. Clerkin, CP

FSIS:IO:EPS:GLLeslie:drd:44-3033:7-9-90
Filename: ep-0026



Sent By: FSIS S&T Tech Support ; 7- -90 ; 8:32AM ;Washington HQ Tech [illegible] 4708765;# 3

LAB CONTROL NO. MF [illegible] (4) 7987

USDA - FSIS IMPORT CHEMICAL, SPECIES & FOOD MICROBIOLOGY LABORATORY ANALYSIS

1. INSPECTION LOCATION CODES: 10 AZ 2165

SERIAL NO. 13531 (54)

2. 440924 LOT 1

4. MIDWESTERN (MC13)

5. PRODUCT CODE AEHBK3

6. ☒ Normal ☐ Special ☐ HOLD

9. HEALTH CERTIFICATE NO. 440924

10. SHIPPING MARKS 440924

11. PRODUCTION DATE / CAN CODE NOT LEGIBLE

12. NO. OF SAMPLES 1

13. COUNTRY OF ORIGIN CANADA 260

14. FOREIGN EST. NO. 224

17. DATE SAMPLED 6-25-90

18. DATE MAILED 6-27-90

19. LABEL APPROVAL DECLARATION OF PERCENT NON MEAT PROTEINACEOUS ADDITIVE IN FINISHED PRODUCT (must be completed by inspector)

a. N.F.D.M. 3 %; b. —; c. SOY PROTEIN CONCENTRATE —; d. —; e. H.V.P. —; f. M.S.S. .25 %; g. —

20. NAME OF PRODUCT AS LABELED AND INGREDIENTS

MORTADELLA NON FAT DRY MILK ADDED
INGR: PORK, PORK FAT, N.F.D. MILK POWDER (DRY SKIM MILK)
SALT, SUGAR, SPICES, PEPPER, M.S.G. ASCORBIC ACID, SODIUM
NITRITE, [illegible]

IMPLISTARIA

FOR NEGATIVE FINDINGS FAX PART 1 TO
[illegible] DEPUTY ADMINISTRATOR FSIS INTERNATIONAL PROGRAMS
FTS: 8-[illegible]
FOR POSITIVE FINDINGS FAX AND ALL PARTS TO: USDA/FSIS
SCIENCE AND TECHNOLOGY SCIENCE FIELD LABORATORIES
ROOM 412 300 12th STREET SW
WASHINGTON, DC 20250 ATTN: [illegible]

21. PRODUCT DISPOSITION ☐ In Compliance ☐ Fail

Initials Date

22. INSPECTOR'S NAME LEONARD DZIUREK

23. BADGE NO. 102

25. ANALYSES REQUESTED AND FINDINGS

☒ FOOD MICRO

26. FOR LABORATORY USE ONLY

MIC 3614 (A)
PF46K

```
3031- 57 (LC method used)
3014- [illegible] (sample in retail inedible casing)
3662- [illegible] (L. monocytogenes +/-)
L. monocytogenes [illegible] detected in 1 sample composit
```

02 01 6-28-90

TYPE OF SAMPLE 54

NA

29. DATE RECEIVED 6-29-90

30. SECURITY SEAL INTACT ☐ YES ☐ NO ☒ [illegible]

CONDITION ON RECEIPT 02/01

33. ANALYST'S CODE 20 [illegible]

FSIS FORM 9540-3 INSPECTOR: See reverse for distribution instructions.

COPY 1 - [illegible] Mail to Import Field Office. ACCREDITED LAB - Fax and mail results to Import Field Office.

07/18/1990 14:16 NC COMPLIANCE DES MOINES* 662 4904 P.03

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

DATE: JULY 18, 1990

Compliance Program
Meat and Poultry Inspection Operations
Food Safety and Inspection Service, USDA

I, the undersigned, representing AA-1 FOOD DIST.
1405 JEFFERY DR., ADDISON, IL 60101
elect to voluntarily destroy for human food purposes the following described product(s):
52 CASES MINUS ONE PIECE OR APPROX.
1,530 LBS. OF MEAT MORTADELLA RECOVERED
FOUND TO BE POSITIVE FOR LISTERIA MONOCYTOGENES.

HELD ~~detained~~ on 7-9-90 at AA-1 FOOD DIST.
1405 JEFFERY DR. ADDISON, IL 60101
by DAVID BROWN & ROBERT D. SHAUB

I understand that the detention action was taken under the authority of the Federal Meat Inspection Act and/or the Poultry Products Inspection Act.

I also understand that the disposal of the products described above will be under the supervision of a representative of the Food Safety and Inspection Service, USDA, without recourse to the Government and that the proposed voluntary destruction of the product(s) does not preclude any legal action that may be found appropriate.

The statements herein are made in full knowledge of the provisions of the U.S. Code, Title 18, Section 1001, which make it a criminal offense to make a willfully false statement or misrepresentation to any department or agency of the United States as to any matter within its jurisdiction.

Sal Circone
Signature

PRESIDENT
Title

United States
Department of
Agriculture

Food Safety
and Inspection
Service

COMPLIANCE PROGRAM
FIELD OPERATIONS DIVISION
1919 S. HIGHLAND AVE., RM. 138D
LOMBARD, IL 60148

July 18, 1990

To: Donald Smart, AOIC
CP, Northcentral Area Office

From: Robert D. Shaub, SCO Robert D. Shaub
CP, Lombard, IL Sub-Area Office

Molteni Foods LTD

Subject: Close out Report on Emergency Programs Recall Number 0026
Canada Est. 224

On July 18, 1990, at AA-1 Food Distributors, 1405 Jeffrey Drive, Addison, Illinois, Compliance Officer Mr. Jesse Peters witnessed the Voluntary Destruction of 52 cases, minus one piece or approximately 1,530 pounds of Meat Mortadella imported from Canada, which was found to be positive for Listeria Monocytogenes. The product was observed being removed from the boxes, packaging material removed, product split and then denatured. The denatured meat product was then placed into a sealed waste container owned by Browning and Ferris Waste Management Co., Chicago, Illinois. The denatured meat product was then transported to a landfill.

Compliance Officer Peters completed and Mr. Sal Ciccone, President, AA-1 Food Distributors, 1405 Jeffrey Drive, Addison, Illinois, 60101, signed FSIS Form 8080-4, Voluntary Destruction For Human Food Purposes.

JUL-06-1990 13:58 FROM IFO#10 TO USDA IP IID HDQ P.03
[illegible] 202 472 [illegible] P.02

EP 0026

IMPORT INSPECTION DIVISION

INITAL RESIDUE AND LISTERIA VIOLATION TRACE BACK

VIOLATIVE COMPOUND & AMOUNT Listeria monocytogenes IFO# 10
COUNTRY CAnAdA AGR I# 440924 DATE 7/6/90
EST.# 224 IFO CONTACT Ron MisKi
PRODUCT NAME Mortadella *SEND COPY ~~OF 9540~~ → & HEALTH CERT.*
Copy of Label Approval

PRESENT LOCATION OF PRODUCT:
CO. NAME A-1 Food Distributor Inc CARTONS [redacted] 52
ADDRESS 1405 Jeffy Dr. WEIGHT [redacted] 1,530.20 lbs
Addison Il
NAME OF MANAGER ETC. Sal Ciccone
PHONE# 708-495-9292
Distributed into commerce

PRESENT LOCATION OF PRODUCT:
CO. NAME CARTONS
ADDRESS WEIGHT
NAME OF MANAGER ETC.
PHONE#

PRESENT LOCATION OF PRODUCT:
CO. NAME CARTONS
ADDRESS WEIGHT
NAME OF MANAGER ETC.
PHONE#

IID STAFF PERSON D. PAlo
E.P.S. STAFF PERSON Dr. Leslie DATE NOTIFIED 7/6/90

CANADA EST. 35 (SCHNEIDER'S)
LISTERIA VIOLATION

Date of lab findings	July 31, 1990
Date IID notified	July 31, 1990
Date Emergency Programs notified	July 31, 1990
Date product located	Product was on "hold" due to previous violation.
Date of disposition of product	

Product on hold for destruction at Holly, NY.

8/1/90

PRELIMINARY EMERGENCY PROGRAMS STAFF NOTIFICATION

*****

DATE : July 31, 1990 **EP NUMBER:** 0033

TIME : 1:20 pm

EST. NO. : 35 (Canada)

EST. NAME : J. M. Schneider, Inc.

EST. ADDRESS: 321 Cortland Ave. East, Kitchener, Ontario
N2G 2W1

PERSON(S) : Marsha N'Dir

NATURE OF INCIDENT:

A monitoring sample (intact) of J. M.'s Deli Best Bologna, 5-lb stick, was positive for L. monocytogenes.

BACKGROUND:
The production lot was on hold-and-test restriction due to previous (6/22/90) violation for listeria in franks. None of the suspect lot was released in commerce.

ACTION: EP Staff will coordinate the disposition of the product.

Plant Management Notified:

Date:
McDougall, IO
Callstrom, ADA
Mina, IMP
Tancredi, POS
Parham, EPID
Clerkin, CP
Foreign Programs
Import Inspection Division
IP, PDD
Microbiology
Northeastern Regional Office
FDA

8/1/90

NOTE TO IID

48 CARTONS OF PRODUCT ON HOLD IN HOLLY , NY, TO BE DESTROYED FOR FOOD PURPOSES UNDER SUPERVISION OF FSIS, IID. EMERGENCY PROGRAMS IS WAITING CONFIRMATION FROM IID THAT THE PRODUCT HAS BEEN DESTROYED.

THE 30 CARTONS ON HOLD AT DETROIT DID HAVE THE SAME PRODUCT CODE AND "BEST BEFORE" DATE BUT IS WAS DUE TO AN ERROR IN STANPING THE PRODUCT. ACCORDING TO AGRICULTURE CANADA THE "BEST BEFORE" DATE SHOULD HAVE BEEN 9/24. THAT PRODUCT WAS RELEASED AFTER IT WAS RESTAMPED TO REFLECT THE PROPER "BEST BEFORE" DATE.

8/13/90
EPS

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

AUG 02 1990

Mr. Pat Dodsworth
J. M. Schnieder Inc.
321 Courtland Avenue East
Kitchener, Ontario N2G 2WI

SPECIAL DELIVERY - CERTIFIED
RETURN RECEIPT REQUESTED

Dear Mr. Dodsworth:

This is to confirm our telephone conversation with you on August 1, 1990, relating to the disposition of J M 's Deli Best Bologna produced by Schnieder Inc.

The product was import inspected and sampled on July 22, 1990, at Est. I-161, Holley Cold Storage F & P Co., Holley, NY. Laboratory analysis of the sample by the Food Safety and Inspection Service (FSIS) revealed contamination of the product with Listeria monocytogenes, a pathogenic organism. The presence of this organism in cooked product poses a public health risk. Therefore, such product can not be used for human consumption and should be destroyed under the supervision of Mr. Robert Coyne, FSIS Import Field Supervisor, Boston, MA.

The following information identifies the product in question:
Product: J M's Deli Best Bologna
Manufacturer: Est. No. 35, Kitchener, Ontario, Canada
Amount of product: 48 cartons/480 pounds
Official Meat Inspection Certificate No.: 492969
Product currently located at:
Est. I-161, Holley Cold Storage F & P Co.
Holley, NY

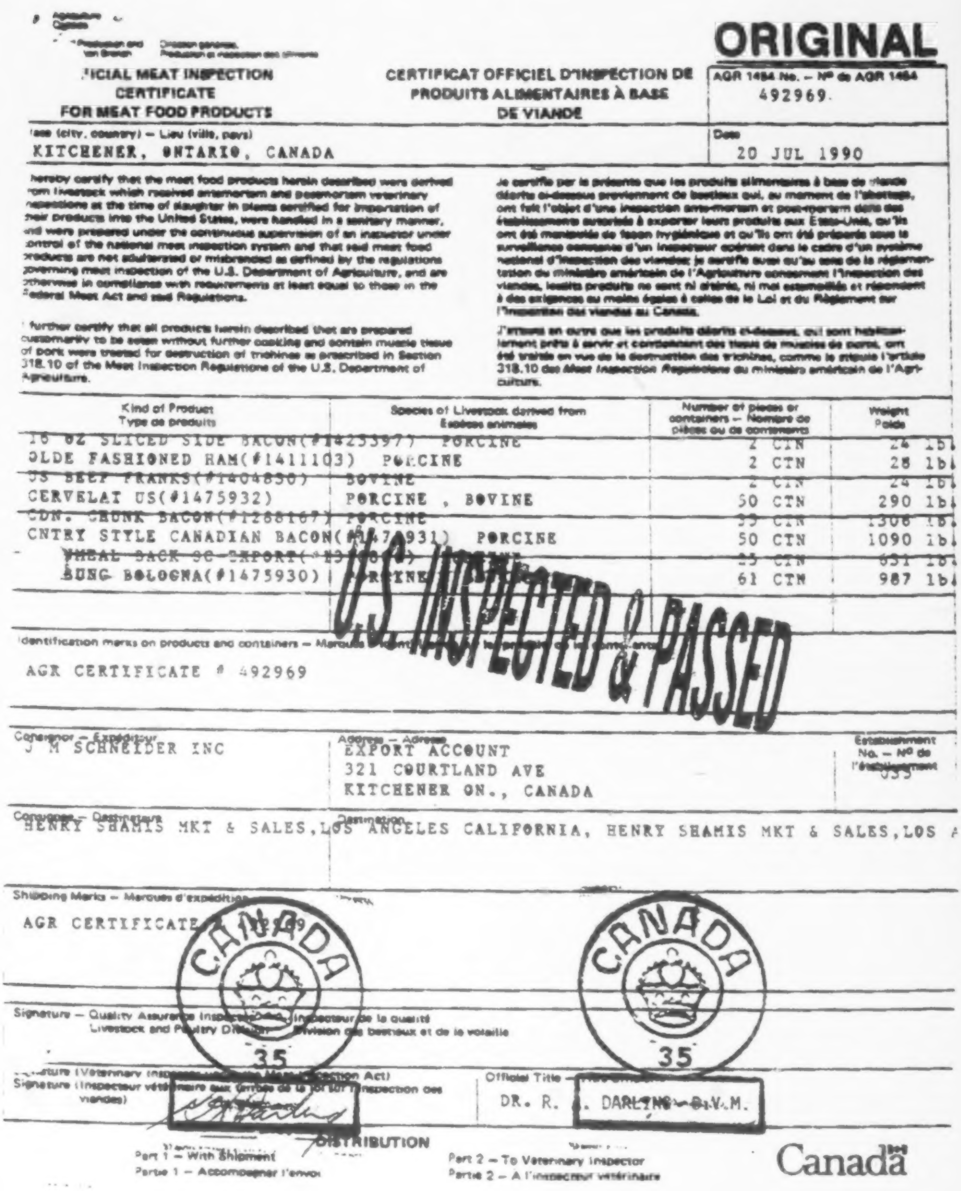
We appreciate your cooperation in this matter. Please let us know should you need further assistance. Our telephone number is (202) 447-3033.

Sincerely,

Earl E. Montgomery, DVM
Director, Emergency Programs Staff
Inspection Operations

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

cc:
R. Callstrom, Acting ADA
M. Mina, IMP
M. Manis, IID
L. Skinner, FPD
R. Johnston, MD
R. Coyne, IFO Supervisor/Boston, MA
EP Casebook



Agriculture Canada

Production and Inspection Branch — Direction générale, Production et inspection des aliments

ORIGINAL

ICIAL MEAT INSPECTION
CERTIFICATE
FOR MEAT FOOD PRODUCTS

CERTIFICAT OFFICIEL D'INSPECTION DE
PRODUITS ALIMENTAIRES À BASE
DE VIANDE

AGR 1484 No. — Nº de AGR 1484: 492969.

lace (city, country) — Lieu (ville, pays): KITCHENER, ONTARIO, CANADA

Date: 20 JUL 1990

hereby certify that the meat food products herein described were derived rom livestock which received antemortem and postmortem veterinary nspections at the time of slaughter in plants certified for importation of heir products into the United States, were handled in a sanitary manner, and were prepared under the continuous supervision of an inspector under control of the national meat inspection system and that said meat food products are not adulterated or misbranded as defined by the regulations governing meat inspection of the U.S. Department of Agriculture, and are otherwise in compliance with requirements at least equal to those in the Federal Meat Act and said Regulations.

further certify that all products herein described that are prepared customarily to be eaten without further cooking and contain muscle tissue of pork were treated for destruction of trichinae as prescribed in Section 318.10 of the Meat Inspection Regulations of the U.S. Department of Agriculture.

Je certifie par la présente que les produits alimentaires à base de viande décrits ci-dessus proviennent de bestiaux qui, au moment de l'abattage, ont fait l'objet d'une inspection ante-mortem et post-mortem dans des établissements autorisés à exporter leurs produits aux États-Unis, qu'ils ont été manipulés de façon hygiénique et qu'ils ont été préparés sous la surveillance constante d'un inspecteur opérant dans le cadre d'un système national d'inspection des viandes; je certifie aussi qu'au sens de la réglementation du ministère américain de l'Agriculture concernant l'inspection des viandes, lesdits produits ne sont ni altérés, ni mal estampillés et répondent à des exigences au moins égales à celles de la Loi et du Règlement sur l'inspection des viandes au Canada.

J'atteste en outre que les produits décrits ci-dessus, qui sont habituellement prêts à servir et contiennent des tissus de muscles de porc, ont été traités en vue de la destruction des trichines, comme le stipule l'article 318.10 des *Meat Inspection Regulations* du ministère américain de l'Agriculture.

Kind of Product Type de produits	Species of Livestock derived from Espèces animales	Number of pieces or containers — Nombre de pièces ou de contenants	Weight Poids
~~16 OZ SLICED SIDE BACON(#1425397)~~	~~PORCINE~~	~~2 CTN~~	~~24 lb~~
OLDE FASHIONED HAM(#1411103)	PORCINE	2 CTN	28 lb
~~US BEEF FRANKS(#1404830)~~	~~BOVINE~~	~~2 CTN~~	~~24 lb~~
CERVELAT US(#1475932)	PORCINE , BOVINE	50 CTN	290 lb
~~CDN. CHUNK BACON(#1288167)~~	~~PORCINE~~	~~55 CTN~~	~~1308 lb~~
CNTRY STYLE CANADIAN BACON(#1474931)	PORCINE	50 CTN	1090 lb
~~WHEAL BACK SC EXPORT(#13[illegible])~~	[illegible]	~~25 CTN~~	~~631 lb~~
BUNG BOLOGNA(#1475930)	PORCINE	61 CTN	987 lb

U.S. INSPECTED & PASSED

Identification marks on products and containers — Marques d'identification sur les produits et les contenants: AGR CERTIFICATE # 492969

Consignor — Expéditeur: J M SCHNEIDER INC

Address — Adresse:
EXPORT ACCOUNT
321 COURTLAND AVE
KITCHENER ON., CANADA

Establishment No. — Nº de l'établissement: 035

Consignee — Destinataire: HENRY SHAMIS MKT & SALES,LOS ANGELES CALIFORNIA, HENRY SHAMIS MKT & SALES,LOS A

Destination:

Shipping Marks — Marques d'expédition: AGR CERTIFICATE # 492969

35

35

Signature — Quality Assurance Inspector, Livestock and Poultry Division — Inspecteur de la qualité, Division des bestiaux et de la volaille

Signature (Veterinary Inspector under the Meat Inspection Act)
Signature (Inspecteur vétérinaire aux termes de la loi sur l'inspection des viandes)

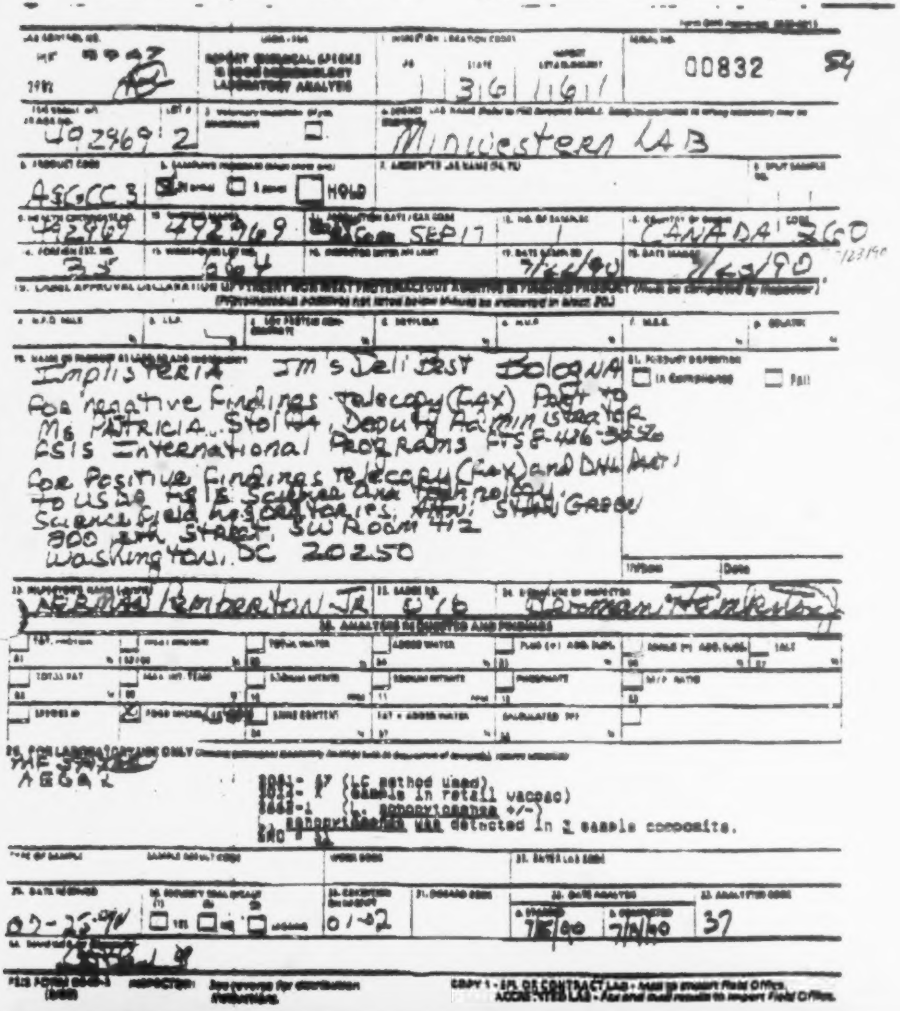
Official Title — Titre officiel: DR. R. [illegible]. DARLING - D.V.M.

DISTRIBUTION

Part 1 — With Shipment
Partie 1 — Accompagner l'envoi

Part 2 — To Veterinary Inspector
Partie 2 — A l'inspecteur vétérinaire

Canada



00832

402969 | 2

Midwestern LAB

ASGCC3 ☒ ☐ ☐ HOLD

402969 | 4929169 | Com SEP17 | 1 | CANADA | 260

35 | 664 | 7/22/90 | 7/23/90

7/23/90

Imp Listeria JM's Deli Best Bologna

☐ In Compliance ☐ Fail

For negative findings telecopy (FAX) Report to Ms PATRICIA Stolfa, Deputy Administrator FSIS International Programs FTS 8-426-3520

For Positive Findings telecopy (FAX) and DHL Air to USDA FSIS Science and Technology Science Field Laboratories, Attn: Stan Green 300 12th Street, SW Room 412 Washington, DC 20250

Initials | Date

HERMAN Pemberton JR | 616 | Herman Pemberton

FOR LABORATORY USE ONLY

3061= 37 (LC method used)
3033= X (sample in retail vacpac)
3062=1 (L. monocytogenes +/-)
L. monocytogenes was detected in 1 sample composite.
SRC = 1

07-25-90 | ☐ ☐ ☐ | 01-02 | 7/25/90 | 7/31/90 | 37

COPY 1 - CONTRACT LAB
ACCREDITED LAB - Fax and mail results to Import Field Office.

[redacted]

ATTACHMENT D

Dr. M. G. Morrissette
Director General
Food Inspection Directorate
Agriculture Canada
930 Carling Avenue
Sir John Calling Building
Ottawa, Ontario   K1A 0C5

Dear Dr. Morrissette:

This is in response to your facsimile of July 7, 1990, titled USDA/Agriculture Canada Joint Import Procedure - Listeria Monitoring. The USDA domestic listeria control program is described in the enclosed FSIS Directive dated February 3, 1989. We expect that sampling by Agriculture Canada of U.S.-origin product would proceed independent of U.S. domestic procedures. Similarly, although we believe that the Canadian listeria control program applied to U.S.-destined finished products must be modified to include product testing, the U.S. import testing program would proceed independent of the Canadian controls. Outlined below is a procedure for communication and follow-up activities related to USDA import listeria testing.

1. Notification: Agriculture Canada inspectors in establishments are aware of listeria sampling by FSIS, as they are aware of all import sampling by USDA since they take the samples. If Ottawa needs to know, you need to have your inspectors report to you.

2. We are now reporting positive results immediately to Ottawa via telephone and follow-up cable. We cannot take on that responsibility for negative results.

3. Turnaround time for results is similar for both domestic and imported product.

4. In the event of a positive finding, the following procedures would also apply:

a. Call and cable to Ottawa;

b. Ottawa advises establishment immediately and informs them of hold and test requirements outlined below;

c. FSIS Emergency Programs contacts establishment representatives to secure full information about production lot and its distribution.

d. Production lots from establishment need to be tested prior to export to us and arrive in U.S. with negative findings certificate. For each lot of product subject to listeria testing, there must be a negative findings document, until negative results from 15 lots have been presented.

Procedures described above are largely in place now. We would expect them to continue. We can discuss further at your convenience.

Sincerely,

Patricia Stolfa
Deputy Administrator
International Programs

Enclosure

USDA/AGRICULTURE CANADA JOINT IMPORT PROCEDURE - LISTERIA MONITORING

1. Notification of appropriate authority (HQ - Washington - Ottawa) of samples collected;

2. Results positive or negative to be immediately reported to Washington/or Ottawa;

3. Turnaround time for test and results similar to domestic program;

4. Should a positive sample be identified, the following procedure shall be followed:

   a) Report to Washington/or Ottawa by phone or by FAX;

   b) Washington/or Ottawa to advise establishment;

   c) Immediate action at plant level to review production methods and clean up procedures;

   d) Production to resume and samples to be collected (finished product);

   e) Samples are identified to production lots.

5. **Exported Products**

   Options Available to Exporters

   a) to be subjected by importing country to routine hold and test procedure - 15 negative shipments;

   b) production lots to be tested prior to export and certified accordingly by exporting country:

      i) A private accredited laboratory or a government laboratory to be used for this purpose;

      ii)Once a production lot has been determined as being negative, sublots could be shipped with copy of the original certificate of analysis.

   c) Establishments not on intensive surveillance for listeria may elect to test production lots and certify accordingly.

6. Tested and certified shipments accompanied by an original certificate or copy of test results, not be subjected to additional testing by the importing country.

July 9, 1990

JUL-09-1990 13:38 FROM FID-AG-CAN-MORISSETTE TO 12024263856 P.03

Agriculture
Canada

FACSIMILE TRANSMITTAL NOTICE

AVIS DE TRANSMISSION DE FACSIMILÉ

To/A: (Name and address/Nom et adresse)

Lester M. Crawford.

Facsimile Telephone No./Nº de téléphone du facsimilé ▶ 202-426-3856-

From/De: (Name and address/Nom et adresse)

M. G Morissette

Facsimile Telephone No./Nº de téléphone du facsimilé ▶

Subject/Objet:

Number of pages/Nombre de pages

________ Short/Courtes ________ Long/Longues

Originals/Originaux

☐ Return by mail
Retournés par la poste

☐ To be picked up at service centre
À reprendre au point de service

Special instructions/Instructions spéciales

As discussed on friday - July 6/90

Signature	Date	Telephone No./Nº de téléphone	Responsibility Centre Code/Code du centre de responsabilité

TOTAL P.03

JUL-09-1990 13:37 FROM FID-AG-CAN-MORISSETTTE TO 12024263856 P.01

Agriculture
Canada

Food Production
and Inspection Branch

Direction générale.
Production et inspection des aliments

Ottawa, Ontario
K1A OC5

Your file Votre référence

Our file Notre référence

July 9, 1990

Dr. Lester Crawford
Administrator
Food Safety & Inspection Services
U.S. Department of Agriculture
Washington, D.C. 20250
U.S.A.

Dear Dr. Crawford:

In keeping with our meeting of July 6, 1990, attached is an outline of the monitoring and reporting procedure for listeria. We are looking forward to an early resolution of this issue.

Yours sincerely,

M. G. Morissette
Director General
Food Inspection Directorate

MGM:ms
Enc.

Canada

July 13, 1990

Mr. Louis Tousignant
Assistant Deputy Minister
Agriculture Canada
Food Production and Inspection Branch
Ottawa, Ontario
K1A 0C5

Dear Mr. Tousignant:

Thank you for transmitting a draft joint statement on *Listeria monocytogenes*. Unfortunately it is not acceptable.

Canada does not have a Listeria control program equivalent to that of the United States (U.S.) because Canada samples the environment whilst the U.S. samples the ready-to-eat food. United States citizens have suffered illness and loss of life throughout this decade by contracting listerosis from food. Ready-to-eat food must not contain the deadly Listeria organisms anymore than it should contain other disease-causing organisms.

The World Health Organization (WHO) communique referenced in the draft simply refers to the biological fact that Listeria is widespread in nature and is not subject to eradication in the same sense as, for example, the smallpox virus. Both recent WHO consultations on food-borne listerosis did, on the other hand, acknowledge the pathogenicity of the organism and the need to eliminate it from ready-to-eat foods through proper hygiene.

We are continuing to work with Dr. Morissette in reconciling the differences in the Canadian and U.S. programs. When this is accomplished we will be prepared to consider a joint statement.

Sincerely,

Lester M. Crawford, DVM, PhD
Administrator

[illegible]

Jw. Crawford

Agriculture
Canada

Food Production
and Inspection Branch

Direction generale.
Production et inspection des aliments

Ottawa, Ontario
K1A 0C5

July 12, 1990

Your file Votre référence

Our file Notre référence

Ms. Jo Ann Smith
Assistant Secretary
Marketing & Inspection Services
U.S. Dept. of Agriculture
Office of the Secretary
Washington, D.C. 20250
U.S.A.

Dear Jo Ann:

This has reference to our telephone conversation of yesterday concerning listeria control in meat products.

As you are aware our control program has been developed in cooperation with our Health Protection Branch colleagues who are equivalent to your Food & Drug Agency. Both USDA and Agriculture Canada programs are of the same nature with regard to their objectives and are adapted to our respective national situation.

We are confident that whilst our respective approaches might differ in some respects, the objective and final results are of the same nature. As noted in our conversation, environmental scanning for listeria in meat processing plants is already in place in Canada and will cover all processing establishments in the very near future. In this way, we will systematically exercise control over the issue at the source as opposed to the product level. Furthermore, we have intensified our import control testing programs to increase testing for listeria, which will enhance the similarity of our respective programs.

In conclusion, I believe, our respective programs do meet the original definition of equivalency of objective and results which have previously been defined between our two agencies.

.../2

copy JAS/JF 7/12

You had proposed, in our telephone conversation, the development of a joint statement on the equivalency of our listeria control programs. Should you still wish to pursue this suggestion, I attach a general first draft, which could of course be amplified, on which I would appreciate receiving your comments. In any event, I am sure you will agree with me it is of the utmost importance that we coordinate statements and keep ourselves informed in a timely way on developments in this area. Dr. Morissette will continue to be our contact in these matters.

Finally, I am looking forward to a positive review of the proposal (copy attached) to harmonize our procedures submitted by Dr. M. G. Morissette, Director General, Food Inspection Directorate to Dr. L.M. Crawford, Administrator, FSIS, as a result of our last meeting. As mentioned, I would appreciate early feedback from you in that regard.

Yours sincerely,

Louis Tousignant

Louis Tousignant
Assistant Deputy Minister

Attachment

July 11, 1990

Draft Joint Statement

Listeria monocytogenes is an environmental contaminant which has been found in soil, vegetation, water, silage, animals and in food. Unlike most other bacteria, listeria can grow in the refrigerator using the abundance of food as a feeding and breeding ground.

USDA and Agriculture Canada do carry out extensive surveys and control of the domestic and imported foods for the presence of listeria. Both systems, while slightly at variance in the details of their approach are of an equivalent nature, providing equal results and, protection to consumers. Both organizations are working together to coordinate even more closely their_testing and reporting system in order to increase the control over this organism. It should be noted that the World Health Organization has determined that the total elimination of listeria may be impossible. Nevertheless, precautions can and should be taken to minimize the risk of infection. The continuing programs of both USDA and Ag. Canada have this objective in mind.

ATTACHMENT E

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10,240.1

2-3-89

LISTERIA MONOCYTOGENES; TESTING PROCEDURES AND SANITATION INFORMATION

I. PURPOSE

This directive provides information on the current sampling and testing program for Listeria monocytogenes (Listeria) under FSIS's Microbiology Monitoring Program. It provides inspection personnel with special instructions for sampling of cooked, ready-to-eat meat and/or poultry products for Listeria and for actions to be taken where samples test positive for this organism.

The attachment to this directive provides guidelines for establishment personnel regarding the cleaning and sanitizing of equipment and facilities and the prevention of Listeria and similar bacterial contaminants.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

Sections 318.2, 318.6 and 318.9 of the Federal meat inspection regulations and sections 381.99, 381.145 and 381.146 of the poultry products inspection regulations.

FSIS Directive 8080.1, Rev. 1, Recall of Meat and Poultry Products

V. POLICY

A. FSIS is especially concerned with the presence of Listeria in cooked, ready-to-eat meat and poultry products because of the potential for serious illness or death among high risk individuals. FSIS has added sampling and testing for Listeria to its current Microbiological Monitoring Programs, and has developed procedures to follow when a Listeria problem is found.

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science Offices, Compliance Offices, TRA, ABB, R&E, AID

OPI: MPIO/EP

B. The purpose of FSIS's Microbiology Monitoring Programs is to collect microbiological data on new meat and poultry products, on products processed under new or different procedures, or on products for which FSIS has limited microbiological data. Monitoring programs are designed to randomly sample meat and poultry products based on the potential for health hazard, spoilage hazard, the volume of product produced or the processing difficulties encountered when producing a particular product. Monitoring programs for specific organisms are conducted over a fixed period of time and are of limited duration. At the conclusion of the particular monitoring program, the data are analyzed and, if necessary, recommendations for adjustments in sanitation or processing procedures or for regulatory actions are made. Examples of current FSIS Microbiological Monitoring Programs include species determinations in both domestic and imported product, and analyses for the presence of salmonella in cooked roast beef, cooked corned beef and raw beef. Monitoring for Listeria in cooked roast beef and cooked corned beef was initiated in September 1987.

C. The Federal Meat Inspection Act and the Poultry Products Inspection Act prohibit the sale or transportation of adulterated or misbranded meat and poultry products. The presence in a meat product or a poultry product of potentially toxic bacterial contamination, such as Listeria, causes a product to become adulterated. Product suspected of being adulterated or misbranded must be retained by the inspector for further inspection and if found to be adulterated or misbranded, is subject to condemnation and disposal under the regulations (§§ 318.2 and 381.145), and may result in criminal prosecution. Product suspected of containing potentially toxic bacterial contaminants that has been distributed from an official establishment is subject to detention or seizure or a voluntary recall.

VI. DEFINITION OF TERMS

A. An **Initial Sample** is a sample of product submitted to an FSIS laboratory under current microbiological monitoring and surveillance programs. Results of this sample will constitute the "Initial Monitoring Sample Result" and will be used to determine whether verification sampling should be instituted.

B. **Like Product** is a particular item prepared from the same species of raw material and having the same product name regardless of brand name or package size. For example, Ace Beef Franks and Jumbo Beef Franks would be considered as like products whereas Ace Beef Bologna would not be considered a like product. Cooked corned beef flats would be considered a like product of cooked corned beef rounds, whereas cooked roast beef would not be considered a like product of either product.

C. A **Lot** is a single day's production of a particular item.

D. A **Corrective Action Letter** is a letter from an establishment operator to the inspector in charge (IIC) which describes in-plant controls or changes and provides sanitation schedules designed to prevent Listeria contamination in future production. The letter should state whether new production of like product will voluntarily be held at the establishment until FSIS laboratory results are received. If the establishment elects to discontinue production of the suspect product for an extended period of time (30 calendar days or longer) and plans no corrective action, this information should be stated in the letter.

E. A **Verification Sample** is a sample of like product collected when an initial sample of product tests positive for Listeria. Unless otherwise directed by the Regional Office, the inspector in charge collects six (6) verification samples from a single production lot of like product.

F. **Audit Samples** are additional samples of like product that are sent to an FSIS laboratory for testing. Audit samples are only needed when samples are sent to a recognized laboratory for testing under the Hold and Test-Restriction.

G. A **Sample Size** for Verification or Hold and Test sampling consists of not less than six (6) intact whole product units per lot.

H. A **Recognized Laboratory** is a commercial or company laboratory which conducts sample analyses for Listeria using a protocol approved by Microbiology Division, Science. Recognized laboratories may be used to analyze samples collected during the "Hold and Test Restriction;" they may also be used to analyze samples submitted by an establishment as part of its monitoring program. Recognized laboratories may not be used to analyze official samples collected under FSIS's monitoring or verification sampling phases. A current list of recognized laboratories is available from the Regional Office. (FSIS has initiated rulemaking to provide regulations concerning the approval and use of recognized laboratories. Once the rulemaking process is completed, this directive will be amended to reflect the results of that action.)

I. **Suspect Product** is like product that may be contaminated with Listeria. All lots of product produced after a verification sample from a lot of like product has tested positive should be considered suspect, unless the lot(s) has been tested by FSIS and found negative for Listeria contamination.

VII. ROUTINE MICROBIOLOGICAL SAMPLING - MONITORING PHASE

A. **Monitoring Samples.** Those establishments that produce certain cooked, ready-to-eat meat and/or poultry products are subject to routine sampling and testing under FSIS's Microbiology Monitoring Program for the presence of microbiological contaminants, including analyses for Listeria. Examples of these types of products include frankfurters, cooked roast beef, cooked corned beef, cooked ham and luncheon meat. Inspectors do not need to submit additional samples for Listeria testing. Results of routine microbiological sampling constitute the Initial Monitoring Sample Result.

B. **Initial Monitoring Sample Result - Positive Finding**

1. The Microbiology Division will notify the Regional Office and the Processing Operations Staff when a monitoring sample tests positive for Listeria.

2. The Regional Office will:

a. Immediately advise the establishment orally of the positive finding and follow up with a written notification.

b. Request that establishment management provide a corrective action letter outlining a corrective action plan to the IIC with a copy to the Regional Director.

c. If the lot has not left the establishment, retain the lot of product represented by the Initial Monitoring Sample Result.

3. The IIC should:

a. Review and discuss with establishment management the FSIS guidelines for cleaning and sanitizing establishment equipment and facilities. (See Attachment 1, Sanitation Information.)

b. Advise establishment management that product not voluntarily held pending verification sample results could be subject to voluntary recall, detention or seizure if the results are positive.

4. The establishment is expected to stop cooking like product as soon as a positive finding for Listeria is reported under Monitoring. A corrective action plan should be implemented by the establishment before cooking of like product is resumed.

VIII. VERIFICATION SAMPLING AND PROCEDURES

A. **Verification Samples Where Corrective Action Taken.** After the establishment's corrective action plan has been implemented and cooking of like product has resumed, the IIC will collect six (6) verification samples from a lot of like product. These samples must be collected from the first lot of product after production has resumed. The IIC will submit these samples to an FSIS laboratory.

B. **Verification Samples Where Corrective Action Not Taken.**

1. If the establishment does not implement a corrective action plan and/or does not stop cooking like product upon notification by

FSIS, the IIC will collect six (6) verification samples from the next available production lot. The IIC will submit these samples to an FSIS laboratory.

2. If the establishment does not produce or does not intend to produce the suspect product for 30 or more calendar days and no corrective action is taken, a special microbiological monitoring program for Listeria will be initiated at that establishment. The Processing Operations Staff will notify the Regional Director of this fact and will provide instructions for sampling under the special monitoring program.

C. **Verification Sampling-Negative Finding.** If verification samples test negative, those lots under voluntary hold will be released and like product will continue to be sampled under FSIS's Microbiology Monitoring Program.

D. **Verification Sampling - Positive Finding**

1. If verification samples test positive, the IIC will:

a. Retain the lot represented by the verification samples if the lot has not been shipped from the establishment.

b. Inform his/her supervisor if any portion of the verification lot has been shipped from the establishment.

c. Consider suspect and retain all lots of like product produced after the verification lot.

d. Request that the establishment provide, in writing, the proposed disposition of the suspect lot(s) and the verification lot.

e. Place subsequent production of like product on the hold and test restriction under paragraph IX.

f. Inform his/her supervisor of any suspect like product shipped from the establishment subsequent to the time the verification samples were collected.

g. Place all lots of recooked product on the hold and test restriction.

IX. HOLD AND TEST RESTRICTION

A. **Application.** The hold and test restriction is instituted by the IIC after verification samples have tested positive for Listeria, providing evidence that such product is suspect. Subsequent production of like product will be tested and retained at the establishment until five (5) consecutive production lots of like product are found to be free of Listeria contamination.

B. Responsibilities

1. The IIC will collect six (6) samples from each lot of like product. The IIC will submit these samples to either a recognized laboratory or an FSIS laboratory. If the samples are sent to a recognized laboratory, one (1) additional sample must be sent to an FSIS laboratory as an audit sample.

2. The Regional Office will advise the IIC on the test results and the disposition of each lot.

3. The disposition of each hold and test lot depends on individual test results. If any hold and test lot tests positive for Listeria, the affected lot will be held at the establishment pending disposition. If the results are negative, the affected lot may be released.

4. When like product is released from the hold and test restriction (after 5 consecutive negative tests), samples of like product no longer need to be taken except as directed by FSIS's Microbiology Monitoring Program.

X. PREVIOUSLY DISTRIBUTED 'SUSPECT' PRODUCT

A. Lots of like product produced after verification samples were collected plus the lot represented by the verification sample will be considered to be suspect lots and may be subject to voluntary recall, detention or seizure.

B. The Emergency Programs Staff will:

1. Notify the establishment that a voluntary recall of affected product is advised.

2. Coordinate activities related to the voluntary recall, including issuing a press release, in accordance with FSIS Directive 3080.1, Rev.1.

XI. SUSPECT PRODUCT UNDER VOLUNTARY HOLD

The IIC will collect six (6) samples of each suspect lot under voluntary hold. The IIC will submit these samples to either a recognized laboratory or an FSIS laboratory. If the samples are submitted to a recognized laboratory, one (1) additional sample must be sent to an FSIS laboratory as an audit sample.

A. Positive sample results

The Regional Office will advise the IIC of the test results and the disposition of each lot.

B. **Negative sample results**

The Regional Office will advise the IIC of the test results and each lot of affected product will be released.

XII. RECALLED PRODUCT

In the event of a product recall by the establishment, the IIC will:

A. Retain all product that is returned to the establishment.

B. Supervise the identification and separation of product by name and lot.

C. Supervise the disposition of the recalled product as directed by the Regional Office.

XIII. MICROBIOLOGICAL INCIDENT SURVEILLANCE SAMPLE (MISS) PROGRAM

The MISS Program is a component of FSIS's Microbiological Surveillance Program. The Microbiological Surveillance Program is initiated at establishments where a problem has been noted through monitoring to determine whether the noted problem has been corrected.

In particular, the MISS Program is initiated whenever an establishment has a positive sample result for Listeria on a verification lot. The MISS Program covers products other than those subject to verification sampling and results are used to evaluate potential problems in these products.

A. Under the MISS Program, the IIC will:

1. Select computer-generated MISS program samples for a designated period of time as directed by the Microbiology Division.

a. If any of these samples test positive and the lot has not left the establishment, retain the lot represented by the positive MISS samples. The Regional Director will notify the establishment of the finding as described in Section VII, B.

b. If these samples test negative, sampling of the product continues under the MISS Program.

W L Horne

Deputy Administrator
Meat and Poultry Inspection Operations

Attachment
Sanitation Information

SANITATION INFORMATION

Although there is nothing new in the following program, limited experience has shown that industrious application of these principles, tailored to meet the specific needs of each establishment and coupled with an intense employee education program to promote good hygiene and product handling practices, will reduce the incidence of Listeria. Random testing for Listeria contamination should be conducted before operations begin to evaluate the effectiveness of the sanitation program, and during operations to assess the degree of contamination that may be present in the environment.

Since Listeria is a frequent contaminant of incoming raw meat products, the separation of raw from cooked processing areas is essential. Each establishment should establish specific controls, tailored to its operations, that will prevent cross contamination. This entails establishing operative sanitation procedures that severely limit any crossover traffic of personnel, frequently disinfecting or sanitizing the work areas, preventing air exchange from raw to cooked areas, and establishing other controls that would prevent cross contamination.

The following items represent some of the omissions observed in sanitation programs. The list is not all inclusive but may be useful to establishment management as a reminder when developing and reviewing a sanitation program for completeness. A person should be designated to monitor and be responsible for each area of concern. Since all items are not applicable in every operation, establishment management should identify the subjects that apply to their operation.

BASIC SANITATION - CLEANUP

1. Dry cleanup. Remove as much product residue as possible without the use of large quantities of water.

2. Rinse. Use warm (140°F.) water to mobilize fats and remove product residue. Minimize splashing.

3. Cleaning Agent. Apply foam, detergent-sanitizer, etc. Allow the appropriate time for action.

4. Rinse. Use warm water and/or 180°F. water. Surfaces should be visibly clean after this step.

5. Sanitizer/Disinfectant. Use chlorine, quaternary ammonium compound, or other appropriate sanitizer as listed in the "List of Proprietary Substances and Nonfood Compounds." For example, use a "D2" compound on food contact surfaces that are freely drained. Use 500 ppm chlorine for 10 minutes or other appropriate disinfectant when possible.

6. Dry area as much as possible. Do not blow aerosols from the floor onto equipment.

CLEANING INSTRUCTIONS AND SCHEDULES

1. Activities during production, breaktime, midshift, end of shift, between shifts, end of day, weekly, monthly.

    a. Cleaning and inspection by cleanup personnel.

    b. Supervisory inspection.

    c. Q. A. Inspection.

2. Identify trouble spots or peculiar areas in facilities and on equipment that should receive special attention.

3. Issue instructions to prevent the recontamination of equipment or facilities when water splashes or air displaces contaminants into clean areas.

4. Fins, coils and drip trays or troughs.

5. Overhead structures-pipes, conduits, light fixtures, beams.

6. Locker rooms, toilets, lunchrooms, offices in the production area, storage area cabinets, shelves.

7. Scale pits, elevator pits.

8. Sewer pots or baskets in drains.

9. Sinks, lavatories - soap, sanitizers, 180°F. water (when required), towels, towel receptacles.

10. Trash receptacles - cans, carts, barrels.

11. Floor mats, stands, walkways.

12. Traffic areas, hallways.

13. Product forks, shovels, knives, hooks, racks.

14. Product tote pans, buckets, trucks, tanks, barrels, chutes, conveyors, covers, shields, tables, trays, cutting boards.

15. Cleaning racks, tubs, trays, carts, sinks and stands.

16. Raw product areas - temperature control or midshift cleanup.

17. Heat-processed product areas - midshift cleanup or acceptable microbiological control and monitoring program.

18. Coolers and freezers.
    a. Cleaning instructions.
    b. Frost control.
    c. Defrosting instructions.
19. Chemicals.
    a. Identify by name and manufacturer.
    b. Mixing instructions.
    c. Instructions for application and proper storage.

PERSONAL HYGIENE

1. Personal effects: care and cleaning and storage of aprons, implements, footware, protective devices and similar materials.

2. Outer garments: protect from contamination before entering department or when leaving department for visits to offices, restrooms, locker rooms, lunch rooms and similar rooms.

3. Clean clothes instructions.

4. Laundry provisions.

5. Hair and beard coverings.

6. Jewelry, cosmetics, buttons, badges.

7. Handwashing and sanitizing.

8. Coughing, sneezing, spitting.

9. Rashes, sores, infections, colds, and other medical problems, that may hazard product or the environment.

10. Bathing and deodorant.

11. Personal habits: smoking or chewing tobacco; gum chewing; scratching; picking nose; stroking hair, mustache or beard; sneezing.

12. Proper handling of gloves to prevent contamination: acquisition, transport to worksite, wearing, cleaning, and replacement.

SANITARY PRODUCT HANDLING

1. Removal of product from shipping containers: protect from staples, filth and extraneous contamination; disposal of cartons, straps, bands.

2. Cooler and Freezer Storage.

   a. protect product in containers from damage.

   b. instructions for disposing of damaged containers.

3. Thawing and tempering frozen product.

4. Movement from storage, to processing, to warehouse, and to shipping.

   a. time/temperature control.

   b. prevention of product abuse.

   c. correct storage procedures to prevent container damage.

5. Product and ingredients rotation - first in, first out.

6. Repackaging, reconditioning, salvaging, reworking instructions.

7. Cross contamination control from raw to cooked by personnel, equipment, and air currents.

8. Sanitary handling and storage of brands, labels, wrappers, packages, bags, films, cartons.

9. Metal detectors, their use and maintenance instructions.

GOOD HOUSEKEEPING PRACTICES AND OPERATIVE SANITATION

1. Trash removal.

2. Inedible product removal - controlled movement of containers and handlers between edible and inedible product areas.

3. Care and cleaning of inedible containers before entry into edible areas.

4. Care and cleaning and storage of edible containers.

5. Hooks and racks for frocks, aprons, hand tools and protective devices.

6. Stands and racks or other protective devices for boxes, films, labels.

7. Product debris control (keep it fresh).

a. Belt washers (where applicable), adjustment and maintenance.

b. Belt squeegees.

c. Continuous sanitization.

d. Spray and wipe.

e. Periodic washoff with water or blowoff with air.

f. Rotation and cleaning of equipment.

8. Laundry - control of soiled garments, operation of laundry, protection of clean garments.

ENVIRONMENTAL CONTROL AND SANITARY MAINTENANCE OF RELATED EQUIPMENT

1. Door closers and seals.

2. Air lock, vestibules, air curtains, fans.

3. Bat wing doors.

4. Plastic strip curtains.

5. Screens on doors, windows and other openings.

6. Condensation control devices and/or procedures.

7. Ventilation system; control of makeup and exhaust air.

8. Air conditioning; filtration, cooling or warming, humidifying or de-humidifying.

9. Zone pressurization to control air movement.

10. Exhaust for heat and steam omitting equipment.

11. Room temperature; thermostat control and security.

12. Pneumatic systems - sanitary maintenance.

13. Traffic control - equipment and personnel.

PEST CONTROL PROGRAM (RODENTS AND INSECTS)

14. Lavatories in work area.
    a. Servicing.
    b. Maintenance.

1. Inside areas; sanitation, maintenance and chemical control.
    a. Processing areas.
    b. Nonprocessing areas.
    c. Inedible areas.
2. Outside premises; sanitation, maintenance and chemical control.
    a. Used equipment.
    b. Refuse control - dumpsters, incinerators.
    c. Livestock docks, pens, alleys.
    d. Roadway dust, puddle and surface drainage control.
    e. Loading docks.
    f. Inedible product and tanking areas.
    g. Odor control - condenser and filter maintenance.
    h. Catch basing (grease) cleaning and maintenance.
    i. Paunch contents, hog hair, feathers.
3. Chemicals.
    a. Identification (Chemical name and manufacturers).
    b. Mixing instructions.
    c. Instructions for proper use.

WATER SUPPLY IDENTIFICATION, PROTECTION AND MAINTENANCE

1. Potable vacuum breakers.
2. Nonpotable (cross connections).
3. Water reuse authorization.

MAINTENANCE PERSONNEL AND OTHERS ENTERING A DEPARTMENT

1. Scheduled maintenance.

2. Movement between edible departments.

3. Movement between inedible and edible product departments.

4. Outer garments and tools as sources of product or environmental contamination.

5. Sanitary disassembly, cleaning and assembly of equipment, (caution: do not clean parts of equipment on the floor).

6. Proper bearing lubrication to avoid product adulteration.

7. Packer white oil: storage, application, and purpose (rust inhibiter; cleaning aid).

8. Emergency maintenance.

    a. Time and temperature control guidelines for product and product residue on equipment.

    b. Cleaning and sanitization of equipment contaminated during maintenance.

9. Electrical units - protection, cleaning, maintenance.

ATTACHMENT F

PROJECT LEADERS - Listeria monocytogenes

Morris, W.	Director Agri-Food Safety Division Food Inspection Directorate Agriculture Canada
Riou, J.	Director Bureau of Field Operations Health Protection Branch Health and Welfare Canada

PROJECT TEAM - Listeria monocytogenes

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1. INTRODUCTION & DEFINITION

Letter to Manufacturers of Ready-to-Eat Meat Products

A Program for the Reduction of Listeria monocytogenes in Ready-to-Eat Meat Products

Listeria monocytogenes has been recognized since the early 1920's as a pathogen which causes severe disease (listeriosis) on rare occasions. It was not until the 1980's that this organism came to the attention of governments, scientists, and the public, as a food-borne, opportunistic pathogen. The organism is particularly objectionable from a public health standpoint as it grows, albeit, slowly at refrigeration temperatures, and it infects compromised target populations, including pregnant women, their fetuses and newborns.

During the past five years, food-borne *Listeria monocytogenes* has been the subject of world-wide scientific investigation and it has also been responsible for national and international crises in public health and international trade. As scientific understanding of *Listeria monocytogenes* improves, it is becoming apparent that well-recognized principles of food technology, applied with diligence at all levels of the food chain, can go a long way to minimize the impact of *Listeria monocytogenes*. This document describes an approach for joint action by Agriculture Canada, Health and Welfare Canada, and the industry, to control *Listeria monocytogenes* in ready-to-eat meats. This modern management approach, using Hazard Analysis and Critical Control Point techniques, is recommended to achieve the desired objectives.

In addition to the above, the public has a role to play in the control of listeriosis, and the Federal Government through Health and Welfare Canada has initiated this education process. This process will be continued through Health and Welfare Canada publications.

It is believed that the diligent application by regulatory agencies and the industry of the principles enunciated in this document, in addition to public education, will help minimize Listeria monocytogenes in ready-to-eat meats.

J.R. Elliot	M.G. Morissette
Director General	Director General
Health Protection Branch	Food Inspection Directorate
Health and Welfare Canada	Agriculture Canada

Definition

Ready-to-eat meat products are those prepared meat products which have been subjected to a manufacturing process sufficient to inactivate or control microorganisms of public health significance and do not require cooking prior to consumption. This would include products such as cooked roast beef, wieners, luncheon meats, fermented meats and jerky.

2. FACT SHEET

1. NAME OF ORGANISM: *Listeria monocytogenes*

   - gram positive rod, non-sporeforming, exhibiting tumbling motility.

   - *L. monocytogenes* is the only truly recognized human pathogen in the genus, although *L. ivanovii* and *L. seeligeri* have been isolated from ill patients.

   a) Salient features of organism and/or disease

      - *Listeria* is a psychrotroph and can therefore grow at refrigeration temperatures.

      - *Listeria* is very widespread in the environment.

      - the organism appears to be slightly more heat tolerant than many vegetative microbes

      - the disease *Listeria* causes is associated with a high case fatality rate.

   b) Source of organism

      - listeriae can be found in soil, sewage, vegetation, stream water and silage.

      - listeriae are also extremely prevalent in the animal population especially in cattle, sheep and chickens.

      - human carriers exist in up to 5% of the general population, but much higher in certain groups such as slaughterhouse workers.

2. DISEASE CHARACTERISTICS

   Name of Disease: Listeriosis

   a) Symptoms

      - in a full-blown disease situation, meningitis, septicemia and central nervous system infection are typical.

      - infection of the pregnant women may cause a mild "flu-like" illness which may result in abortion, premature delivery, still-birth, and early or late perinatal sepsis.

      - gastrointestinal symptoms such as nausea, vomiting and diarrhea may preceed more serious forms of listeriosis or can be the only symptoms occurring.

b) Incubation Period

- appears to vary from a few days to 35 days.
- (range 1-91 days).

c) Target population

- pregnant women and their fetuses, newborns, the elderly, recipients of immunosuppressive or corticosteroid therapy, those with underlying diseases such as cancer, hepatitis, diabetes mellitus and alcoholism and those undergoing long-term hemodialysis.

d) Case fatality

- the case fatality rate in foodborne outbreaks has averaged 30%.

3. MINIMUM INFECTIOUS DOSE

- although unknown at this time it is thought that less than 1,000 total organisms can cause illness in susceptible people.

4. FOODS ASSOCIATED WITH DISEASE

- raw milk, pasteurized milk*, human breast milk, cheese, ice cream*, vegetable, rennet, coleslaw, raw vegetables*, hot dogs, chicken, pâté, salted mushrooms, fish.

5. RELATIVE PREQUENCY IN CANADA

- although only 15 cases of listeriosis are usually reported per year in Canada, with a surveillance program recently initiated, in 1987, 44 cases were reported, with 18 deaths occurring; in 1988, 60 cases with 20 deaths were reported.
- the U.S. has estimated that as many as 1600-1700 cases/year may occur with at least 450 deaths, not including stillbirths.

6. RECENT OUTBREAKS

Location, Year	Food	No. of Cases (and deaths)
Boston, 1979	Lettuce, celery, tomatoes	23 (5)
Nova Scotia, 1981	Coleslaw	41 (18)
Massachusetts, 1983	Pasteurized milk	49 (14)
California, 1985	Mexican-style soft cheese	142 (48)
Canton of Vaud, Switzerland, 1983-87	Soft cheese	111 (31)

*only epidemiologically implicated

FACT SHEET ON *LISTERIA MONOCYTOGENES*

1. TEMPERATURE RANGE FOR GROWTH

- -0.4°C to 50°C
- generation times (approximate)

4°C - 29-45 h
8°C - 9-14.5 h
13°C - 4.5-7 h
21°C - 1.75-2 h
35°C - 41 min

2. pH

Minimum pH for growth under ideal conditions (HCL as acidulant)
20-30°C - 4.4 4°C - 5.2 7-10°C - 4.6
cabbage juice - pH ≤ 4.8 lethal
uncultured whey stored at 6°C - no growth at or below pH 5.4

3. MINIMUM WATER ACTIVITY FOR GROWTH UNDER IDEAL CONDITIONS

4°C - 0.94 30°C - .925

4. SALT (NaCL)

Will grow in 10% NaCL at 4°C, 12% NaCL at 30°C.
Can remain viable in NaCL solutions of 25.5%.

5. FREEZING

Freezing of either meat, poultry, or raw milk appears to have no significant detrimental effect on the organism.

6. HEATING

$D_{60}\,^{\circ}C$ values - chicken - 5.0 to 5.3 min; beef slurry - 6.3 to 8.3 min.
Hot dogs - 71°C internal - 3 log reduction;
68.5°C internal - 2 log reduction.
Fermented Sausage Mix $D_{62}\,^{\circ}C$ - 7.06 min; $D_{64}\,^{\circ}C$ - 2.28 min.
Mean Z value - 6.7°C

7. PREVALENCE OF L. MONOCYTOGENES IN MEAT AND POULTRY PRODUCTS

Minced ground beef or pork - 30-95%
Fermented sausages - 5-23%
Raw poultry - 14.7-60%
Ready-to-eat meat products (producing plants) - 39% of establishments sampled in 1988 were positive

3. POLICY & IMPLICATIONS OF CONTAMINATION

Health and Welfare Canada
Santé et Bien-être social Canada

Health Protection Branch
Direction générale de la protection de la santé

89-1

ADMINISTRATIVE COMPLIANCE POLICY

SUBJECT: FOODS CONTAMINATED WITH LISTERIA MONOCYTOGENES

BACKGROUND

Listeria monocytogenes is a bacterial pathogen that is widely distributed in nature. It has been isolated from fecal specimens of healthy animals and man, as well as from sewage, silage, soil, fertilizer, and vegetable matter. Important characteristics of this organism are its ability to grow at temperatures of 3°C (or less) to 45°C, at pHs of 5.0 - 9.6, a water activity of 0.94 or higher, and in high salt concentrations (of perhaps greater than 10%).

It is estimated that up to 5% of humans may carry L. monocytogenes in their intestines without ill effects. However, this organism has for many years been recognized as occasionally causing an infection known as listeriosis. Several modes of transmission have been identified: mother to foetus infection in utero or infection at childbirth, infant to infant, animal to human and, most recently, food to human transmission.

POLITIQUE ADMINISTRATIVE - SURVEILLANCE DE LA CONFORMITÉ

OBJET: ALIMENTS CONTAMINÉS PAR LISTERIA MONOCYTOGENES

GÉNÉRALITÉS

Listeria monocytogenes est une bactérie pathogène très répandue dans la nature. On a pu l'isoler à partir d'échantillons d'excréments d'animaux et d'humains en santé, ainsi que dans des eaux d'égout, du fourrage ensilé, de la terre, des engrais et des matières végétales. Parmi les caractéristiques importantes de cet organisme, notons sa propriété de croître à des températures allant de 3°C (ou moins) à 45°C, à des pH de 5,0 à 9,6 à une activité de l'eau d'au moins 0,94, et dans des milieux très salins (concentrations peut-être supérieures à 10%).

On estime que L. monocytogenes pourrait être présent dans les intestins de jusqu'à 5% des gens sans effets nocifs. Depuis de nombreuses années, on sait toutefois qu'il arrive au microorganisme de provoquer une infection appelée "listériose". Plusieurs modes de transmission ont été identifiées, à savoir: de la mère au foetus in utero, ou de la mère au bébé à la naissance; d'un nouveau-né à un autre; d'un animal à un humain; et, récemment d'un aliment à un humain.

Canada

Serious infections of *L. monocytogenes* are manifested by septicemia and meningitis, and may result in death. The highest incidence of listeriosis is amongst neonates, the elderly and immunocompromised individuals. A significant proportion of cases are also amongst pregnant women, where passage of the organism through the placenta may cause abortion, stillbirth or perinatal septicemia and meningitis in the newborn baby. Infection of healthy, non-pregnant adults is relatively rare. Mortality in serious, untreated cases of listeriosis may exceed 25 percent, particularly amongst predisposed groups.

The recognized number of human listeriosis cases is increasing in many countries. This may be simply the result of improved reporting procedures implemented because of heightened interest in this illness by the public health and medical communities, or it may be a real change reflecting an emerging prevalence in the environment including food, and consequently more frequent human exposure. The rise in incidence may also find its cause in increased susceptibility in the human population (e.g. persons suffering from cancer, AIDS; the elderly; transplant patients). Despite the conduct of in-depth epidemiological investigations of many cases of listeriosis, the actual cause is seldom identified. The role of contaminated food as a vector of this illness is, therefore, still relatively obscure, except for the four major foodborne outbreaks which have been documented in North America and Europe. These were attributed to coleslaw from cabbages believed to have been contaminated with untreated manure (Nova Scotia, 1981), milk probably

Les infections graves attribuables à *L. monocytogenes* se manifestent par une septicémie et une méningite, et peuvent être mortelles. L'incidence de la listériose est à son plus haut chez les nouveau-nés, les personnes âgées et les immunodéprimés. En outre, un pourcentage important des cas est recensé chez les femmes enceintes, le microorganisme pouvant alors - par passage transplacentaire - être cause d'avortement, de mortinaissance ou de septicémie et de méningite périnatale chez le nouveau-né. L'infection est relativement rare chez des adultes en santé, exception faite des femmes enceintes. Dans les cas graves et non traités, la mortalité peut être supérieure à 25%, particulièrement chez les groupes prédisposés.

De nombreux pays recensent de plus en plus de cas de listériose humaine. Cette hausse s'explique peut-être tout simplement par les améliorations apportées aux méthodes de déclaration en raison de l'intérêt accru des milieux de la santé publique et de la médecine pour cette maladie, mais il s'agit peut-être aussi d'un changement réel qui reflète une prévalence accrue du microorganisme dans l'environnement (notamment dans les aliments) et, par conséquent, l'exposition humaine plus fréquente. La hausse de l'incidence pourrait aussi être attribuable à une augmentation de la sensibilité chez la population humaine (p. ex., personnes atteintes de cancer, de sida; personnes âgées; tranplantés). Même si des enquêtes épidémiologiques poussées sont menées sur de nombreux cas, la cause véritable est rarement identifiée. Le rôle des aliments contaminés comme vecteurs de la maladie reste donc plutôt obscur, sauf en ce qui concerne quatre flambées importantes qui ont été documentées en Amérique du Nord et en Europe et dans lesquelles on a incriminé du *coleslaw*

contaminated after pasteurization (Massachusetts, 1983) and soft cheese made from both raw and pasteurized milk (California, 1985, and Switzerland 1983-87). A very few other cases throughout the world have been epidemiologically associated with contaminated foods. These have been sporadic, with no clustering in time and place.

There have been relatively few confirmed cases of listeriosis in Canada. The total for 1988 was 60, compared with 44 in 1987. The only food related outbreak in this country was that from contaminated coleslaw as noted previously. In 1988 a single case of listeriosis in a 66 year old man was directly linked to imported soft cheese.

There is increasing evidence that L. monocytogenes is truly ubiquitous in nature. As a result, it is not surprising that this bacterium has also been found in a wide variety of foods including meat, poultry, dairy, marine and vegetable products. International experts participating in the World Health Organization's Informal Working Group on Foodborne Listeriosis (February 1988) concluded that "the total elimination of L. monocytogenes from all food is impractical and may be impossible". This situation is of mounting concern to food regulatory agencies, the food industry, and the public throughout the world because of the many unknowns associated with the public health significance of this organism in various foods. These primarily relate to the infective dose, the virulence of various strains, the

(salade de chou) préparé avec du chou qui aurait été contaminé par du fumier non traité (Nouvelle-Écosse, 1981); du lait probablement contaminé après avoir été pasteurisé (Massachusetts, 1983); ainsi que des fromages à pâte molle préparés avec du lait cru et du lait pasteurisé (Californie, 1985; et Suisse, 1983-1987). A l'échelle mondiale, ce sont à peu près les seuls cas qui ont été associés épidémiologiquement à des aliments contaminés. Les quelques autres ont été sporadiques, sans grappe spatio-temporelle.

Au Canada, il y a eu relativement peu de cas confirmés de listériose. En 1988, le total était de 60; et en 1987, de 44. La seule flambée dont l'origine alimentaire a été confirmée mettait en cause de la salade de chou contaminée (voir plus haut). En 1988, un seul cas de listériose a été lié directement à un aliment; il s'agissait d'un homme de 66 ans tombé malade après avoir consommé du fromage à pâte molle importé.

Nous avons de plus en plus de preuves de la distribution vraiment omniprésente de L. monocytogenes dans la nature. Il ne faut donc pas s'étonner si cette bactérie a été retrouvée dans une vaste gamme d'aliments, notamment de la viande, de la volaille, des produits laitiers, des produits de la mer, et des légumes. Selon des experts internationaux participant au groupe de travail non officiel de l'Organisation mondiale de la santé sur la listériose alimentaire (février 1988), il est peu réaliste, voire impossible, d'éliminer totalement L. monocytogenes de tous les aliments. Devant cette situation et en raison des nombreuses inconnues liées à l'impact sur la santé publique de la présence de la bactérie dans les aliments, les organismes de réglementation, l'industrie alimentaire et le grand public du monde entier sont vulnerability of certain segments of the population, and the role of various foods in facilitating infectivity.

FACTORS CONSIDERED IN THE POLICY DEVELOPMENT

The following are important factors considered in the development of this policy to ensure a prudent but practical approach to minimizing risks from foodborne listeriosis while scientific and epidemiological studies continue.

1. The three foods implicated in the four major outbreaks of listeriosis world-wide are all products in which L. monocytogenes can grow to high numbers before consumption. The policy should therefore consider the potential for growth of L. monocytogenes in a particular food, based on criteria such as pH, water activity, and the presence of preservatives.

2. The coleslaw related outbreak was a somewhat unique situation in that the implicated food may have been inadequately acidified and is believed to have been directly contaminated with manure from sheep suffering from listeriosis.

de plus en plus inquiets. Les questions à résoudre portent principalement sur la dose infectante, la virulence de diverses souches, la vulnérabilité de certains segments de la population, et le rôle facilitateur de certains aliments à l'égard de l'infectivité.

FACTEURS PRIS EN CONSIDÉRATION DANS L'ÉLABORATION DE LA POLITIQUE

Le texte qui suit présente des facteurs importants dont il est tenu compte dans l'élaboration de la politique, afin de garantir une approche prudente, quoique pratique, qui permettent de minimiser les risques de listériose d'origine alimentaire pendant que les études scientifiques et épidémiologiques se poursuivent.

1. Les trois types d'aliments incriminés dans les quatre principales flambées recensées dans le monde sont tous des produits dans lesquels il peut y avoir prolifération de L. monocytogenes en nombres élevés avant la consommation. Par conséquent, la politique devrait tenir compte du potentiel de croissance de L. monocytogenes dans un aliment donné, d'après des critères tels que le pH, l'activité de l'eau, et la présence d'agents de conservation.

2. La flambée associée à une salade de chou avait ceci de particulier que l'aliment incriminé était peut-être insuffisamment acidifié, et passe pour avoir été contaminé directement par du fumier de moutons atteints de listériose.

3. Three of the four major outbreaks involved dairy products, which indicates that contamination of these foods with L. monocytogenes is of particular public health significance. This is supported by preliminary research evidence that milk (or its constituents) may provide enhanced penetration of the gastrointestinal mucosa by L. monocytogenes.

4. The foods associated with listeriosis have been those in which L. monocytogenes could grow to high numbers. This suggests that any such product may be capable of causing listeriosis, although the likelihood of any one contaminated food resulting in an illness, based on current case data from around the world, must be considered as remote.

5. At this time, there is little evidence that low numbers of L. monocytogenes in a food will cause listeriosis, even in susceptible individuals.

COMPLIANCE POLICY

1. Contamination of dairy products which will support growth of L. monocytogenes (e.g. soft cheese, pasteurized milk) shall be considered life-threatening and recall action shall be requested immediately for any product in distribution. The recall shall be assigned Class I status, requiring consideration of a health alert.

2. Contamination with L. monocytogenes of dairy products which will not support growth (e.g. ice cream, hard cheese) shall result in an immediate request for recall action for any product in distribution. The recall shall be assigned Class II status.

3. Trois des quatre principales flambées mettaient en cause des produits laitiers. La contamination de ces produits par L. monocytogenes est donc particulièrement importante pour la santé publique. Ce constat est d'ailleurs appuyé par des résultats préliminaires de recherche selon lesquels le lait (ou ses contituants) peut faciliter la pénétration de la muqueuse gastro-intestinale par L. monocytogenes.

4. Les aliments qui ont été associés à la listériose sont tous des aliments qui permettent à L. monocytogenes de croître en nombres élevés, ce qui laisse entendre que tout produit de ce type pourrait être susceptible de provoquer la listériose, encore que, d'après les données actuelles sur des cas du monde entier, la probabilité qu'un aliment contaminé entraîne la maladie doit être considérée comme faible.

5. Il n'y a présentement pas beaucoup de données qui permettent de dire que la présence de faibles nombres de L. monocytogenes dans un aliment entraînera la listériose, même chez des sujets sensibles.

SURVEILLANCE DE LA CONFORMITÉ

1. La contamination de produits laitiers qui permettra la prolifération de L. monocytogenes (p. ex. fromage à pâte molle, lait pasteurisé) sera considérée comme un risque mortel, et tout produit sur le marché sera rappelé sans délai. On attribuera au rappel un statut de 1re classe, et on envisagera la publication d'une alerte sanitaire.

2. La contamination par L. monocytogenes de produits laitiers qui ne permettra pas la prolifération de la bactérie (p. ex., crème glacée, fromage à pâte dure) entraînera immédiatement une demande de rappel de tout produit sur le marché. On attribuera au rappel un statut de 2e classe.

3. Contamination with L. monocytogenes of any ready-to-eat food (not covered in point #1) which will support growth shall result in an immediate request for recall action for any product in distribution. The recall shall be assigned Class II status.

4. Contamination with L. monocytogenes of any ready-to-eat food which will not support growth shall result in an immediate request for recall action for any product in distribution if manufacturing facilities and operations are deemed to violate Section 7 of the Food and Drugs Act. The recall shall be assigned Class II status.

5. A health alert shall be considered for any ready-to-eat food contaminated with L. monocytogenes which is being recalled, if there is believed to be heightened or increased risk to the public by virtue of factors such as the level or incidence of L. monocytogenes in the food, the source of the contamination (e.g. faecal material) or the food is specifically marketed to a vulnerable segment of the population.

6. All sectors of the food industry (production, manufacturing, food service and retail) are to be encouraged to make every effort to market foods free of L. monocytogenes. This may require modified facilities and operating practices (such as a more severe thermal treatment, increased frequency and thoroughness of cleaning and sanitizing of the equipment and environment, and improved temperature controls). The presence of L. monocytogenes in any food as a result of poor sanitation or non-adherence to "good manufacturing practices" is unacceptable.

3. La contamination par L. monocytogenes d'un aliment prêt à consommer (non mentionné au point 1) qui permettra la prolifération de la bactérie entraînera immédiatement une demande de rappel de tout produit sur le marché. On attribuera au rappel un statut de 2e classe.

4. La contamination par L. monocytogenes d'un aliment prêt à consommer qui ne permettra pas la prolifération de la bactérie entraînera immédiatement une demande de rappel de tout produit sur le marché, si l'on juge que les installations et les pratiques de fabrication sont non conformes à l'article 7 de la Loi sur les aliments et drogues. On attribuera au rappel un statut de 2e classe.

5. On envisagera de publier une alerte sanitaire lorsqu'un aliment prêt à consommer contaminé par L. monocytogenes fait l'objet d'un rappel, si l'on juge que le risque pour le public est accru en raison de facteurs tels que le taux ou l'incidence de L. monocytogenes dans le produit, la source de la contamination (p. ex., matières fécales), ou si le produit est destiné expressément à un segment vulnérable de la population.

6. Tous les secteurs de l'industrie alimentaire (producteurs, fabricants, restaurateurs et détaillants) doivent être encouragés à faire de leur mieux pour que les produits mis en marché soient exempts de L. monocytogenes. Pour cela, ils devront peut-être modifier certaines installations et pratiques (p. ex., accentuer la rigueur du traitement thermique, augmenter la fréquence et la minutie du nettoyage et de la désinfection de l'équipement et du milieu, et améliorer les régulateurs de température). La présence de L. monocytogenes dans un aliment en raison d'une hygiène médiocre ou du non-respect des "bonnes pratiques de fabrication" est inacceptable.

ENFORCEMENT ACTION

There is no specific prohibition in the Food and Drugs Act and Regulations against the presence of *L. monocytogenes* in a food product. For this reason, any enforcement action on listeria contaminated foods is to be taken under Section 4(a), 4(e) or 7 of the Act.

Food Directorate, and
Field Operations Directorate
Health Protection Branch
Health and Welfare Canada

December 1989 (replaces April 1988)

MESURES COERCITIVES

Dans la Loi et les Règlements sur les aliments et drogues, on ne trouve aucun interdit précis contre la présence de *L. monocytogenes* dans un produit alimentaire. Toute mesure coercitive doit donc être prise au sujet d'aliments contaminés par *Listeria*, en vertu de l'article 4(a), 4(e) ou 7 de ladite Loi.

Direction des aliments, et
Direction des opérations régionales
Direction générale de la protection de la santé
Santé et Bien-être social Canada

Décembre 1989 (remplace avril 1988)

LISTERIA MONOCYTOGENES

IMPLICATIONS OF CONTAMINATION OF READY-TO-EAT MEAT PRODUCTS

1. Industry is expected to follow good manufacturing practices and adopt means to eliminate sources and vectors of contamination.

2. Contamination with *L. monocytogenes* of any ready-to-eat meat which will support growth shall result in an immediate request for recall action for any product in distribution. The recall shall be assigned Class II status.

3. Contamination with *L. monocytogenes* of any ready-to-eat meat which will not support growth shall result in an immediate request for recall action for any product in distribution if G.M.P.'s are not followed. The recall shall be assigned Class II status.

4. The issuance of a public alert shall be considered for any ready-to-eat meat contaminated with *L. monocytogenes* which is being recalled if there is believed to be heightened or increased risk to the public, ie. the food is specifically marketed to a vulnerable segment of the population.

5. In any case, where the product is epidemiologically linked to an outbreak of listeriosis it will be subject to a Class I recall action with consideration of a public alert.

NOTE: The above does not eliminate the responsibility of manufacturers and others to comply with provisions of relevant Federal food legislation.

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4. GOOD MANUFACTURING PRACTICES

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GOOD MANUFACTURING PRACTICES

REDUCING THE INCIDENCE OF LISTERIA MONOCYTOGENES IN READY-TO-EAT MEAT PRODUCTS

The elimination of Listeria monocytogenes from a ready-to-eat meat processing plant is not a simple task. It requires a comprehensive approach that considers all facets of the manufacturing operation. This document, "Good Manufacturing Practices - Reducing the Incidence of Listeria monocytogenes in Ready-to-Eat Meat Products", is such an approach.

These Good Manufacturing Practices are recommendations. They do not cancel or replace the applicable legislation, enforced by Agriculture Canada or Health and Welfare Canada. These GMPs and those found in "Code of Practice - General Principles of Food Hygiene for use by the Food Industry in Canada" (see Appendix A), are a series of design features, practices and procedures that, if followed, will result in a more hygienic and sanitary establishment.

A. FACILITY AND DESIGN REQUIREMENTS

Poorly designed and maintained facilities provide environmental conditions which can support the growth of Listeria monocytogenes and, consequently, act as a reservoir of contamination.

1. General Requirements

*Building and facilities should be of sound construction and maintained in good repair. Adequate working space should be provided to allow for satisfactory performance of all operations.

*Floors and walls should be smooth, water-proof, easy to clean and free from cracks, crevices and other uncleanable surfaces which may harbour large microbial populations. Floors should be sloped sufficiently to allow liquids to drain to the outlet and be kept as dry as possible. Drains should be large enough to handle the peak flow and should be constructed so that they can be cleaned and sanitized daily.

*Ceilings should be designed, constructed and finished to prevent the accumulation of dirt, be easily cleaned and minimize condensation. Overhead structures, fittings and pipes should be accessible for cleaning. They should be insulated, where appropriate, to prevent the formation of condensation. If refrigeration units are used, they should be directly drained.

.../2

*Adequate and conveniently located changing facilities, toilets and hand washing/drying should be provided. All handwashing facilities should be of the remote control type (timed, foot- or knee-activated) and directly drained.

*Buildings and facilities should be designed to provide separation by partition, location or other effective means, between those operations which may cause cross-contamination. The product flow should be evaluated to identify possible cross-contamination of finished products by raw products, employees or other environmental factors. A continuous forward flow progression must be maintained throughout handling.

*All equipment and utensils used in food handling areas should be designed for easy and repeated cleaning and disinfection and should not trap moisture and food debris. Surfaces should be smooth and free from pits and crevices. All welded equipment should have continuous, smooth and evenly welded joints. Contamination in areas in close proximity to the processing line are critical. Stationary equipment should be installed in such a manner as to permit easy access and thorough cleaning.

*Adequate facilities for cleaning and disinfection of equipment and utensils should be provided. These should be located and designed to prevent contamination of foods during cleaning. Separate facilities should be provided for raw and cooked product equipment.

*A storage area should be provided for the storage of waste (including floor scrapings) and inedible material prior to removal from the establishment. These facilities should be designed to prevent contamination of food, equipment and buildings.

2. Air Handling Systems

*Buildings and facilities should be designed with air movement taken into consideration. Positive pressure should be maintained in the finished processing and packaging rooms. Air should flow from the finished processing and packaging rooms to the outside or to the raw processing section.

*Adequate ventilation should be provided to prevent excessive heat, condensation, dust and to facilitate the removal of contaminated~~ air and~~ steam.

.../3

*Air supply should be filtered to remove contaminating moisture and particulate matter.

3. Maintenance

*A scheduled preventative maintenance program should be developed and implemented. This program should include inspection of processing equipment, facilities and utensils on a regular basis and servicing those before problems occur.

*An effective maintenance program should identify and remedy identified areas which accumulate and trap moisture, food debris; cannot be easily cleaned; and which require repair.

.../4

B. HYGIENE REQUIREMENTS

An effective, thorough cleaning and disinfection program is a primary control over Listeria monocytogenes contamination of the processing environment.

1. General Requirements

*All food contact surfaces in processing and handling areas should be cleaned and sanitized on a daily basis or more often when required. Include such areas as conveyors, belts, tables, slicers, peelers and gloves.

*All other environmental surfaces such as walls, floors, air handling systems, filters, coils, pans etc. should be inspected, cleaned and sanitized as directed by the scheduled program.

*Where possible and safe to do so, have the equipment running during cleaning and sanitizing for complete exposure to chemicals.

*Hallways common to raw and finished product areas must be kept clean and dry.

*Changing facilities and toilets should be kept clean at all times.

*The environment should be kept as dry as possible. The use of steam and water should be minimized.

*A written schedule should be developed to monitor the frequency and to measure the effectiveness of the cleaning regime in place.

2. Cross-Contamination

*Items which absorb water (rags, sponges) form potential harbourages for microorganisms. Mops, squeegees, scouring pads, hoses and condensate removal equipment are important sources of contamination. Eliminate absorbent brooms with ones with plastic handles and bristles which can be cleared and sanitized. Replace rags with single use disposable wipes and discard scouring pads daily.

*Adequate precautions should be taken to prevent food from being contaminated by Listeria monocytogenes during cleaning and disinfection of rooms, equipment or utensils.

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3. Review and Monitoring of Hygiene Program

*Review cleaning and sanitizing programs on a regular basis by formal visual inspection and review of cleaning schedule records. Confirm procedures for proper selection of detergents, sanitizers, temperatures, pressures and concentration to ensure that they are effective against *Listeria monocytogenes* and other pathogens.

*The schedule for cleaning and sanitizing should be validated by microbiological monitoring of the effectiveness of those operations using both indicator organisms and testing the cleaned environment for *Listeria monocytogenes*.

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C. PERSONAL HYGIENE REQUIREMENTS

An effective environmental sanitation program includes employees trained and knowledgeable in good personal hygiene practices.

1. General Requirements

*Every person in a food handling area should, at all times, wear suitable protective clothing including head covering and footwear. These should be maintained in a clean condition consistent with the nature of the work in which the person is engaged.

*Every employee should change outer clothing daily or more often as required. Protective equipment, aprons and gloves should be washed and sanitized or replaced on a daily basis or when soiled. Aprons and similar items should not be washed on the floor.

*Maintenance personnel must change outer clothing prior to entering post-heat processing areas. They must wear the same colour coding worn by those in the designated area. Equipment which has been repaired or adjusted in processing areas must be cleaned and sanitized prior to resuming the operations.

*Every person engaged in a food handling area should wash his/her hands before commencing work, upon returning to work, after contacting unclean and contaminated material and whenever otherwise necessary. Notices requiring hand washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

2. Cross-Contamination

*Establish traffic patterns to control movement of personnel, meat containers, meat, ingredients, pallets and refuse containers from raw to finished product areas. To help control employee traffic, each employee should be assigned an identifying code (colour, insignia on hat or collar, etc.) identifying their area of work.

*Clean uniforms and shoes/boots should be worn only in the plant and not to and from home. Waterproof footwear should be cleaned and sanitized when leaving and upon returning to the work stations. Footbaths, when properly maintained can be an effective means of controlling the spread of microorganisms in a food processing environment.

.../7

*If employees working in raw product areas are required to work in finished product areas, they should change outer clothing, wash hands, change gloves, and clean and sanitize footwear, equipment and utensils before entering that area.

*Personal equipment (knives, aprons, protective gloves) should not be stored in lockers with street clothes. It should be cleaned and sanitized before storage and again before returning to the work station.

*Precautions should be taken to prevent visitors to food handling areas from contaminating food with Listeria monocytogenes. These must include the use of protective clothing.

3. Training

*Plant managers and supervisors should set the example. All employees should feel a sense of personal responsibility for the safety and quality of food products.

*Plant management should provide continuing training of every food handler to ensure that correct and hygienic food handling practices are employed, which will contribute to the reduction of Listeria monocytogenes contamination. Instruction should include relevant parts of this code.

*The sanitation crew should be trained to identify unsanitary conditions which could lead to cross-contamination with either cleaning procedures, cleaning equipment or cleaning chemicals.

*Responsibility for ensuring compliance by all personnel, with all requirements of personal hygiene, should be specifically assigned to trained, competent supervisors.

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D. PROCESSING REQUIREMENTS

A preventive approach, which shifts the emphasis from inspection and testing of the final product to raw material and process control is recommended. The Hazard Analysis/ Critical Control Points (HACCP) technique is essentially a preventive, forward-looking approach which is intended to prevent problems before they occur rather than find them in the finished product. (See Appendix B for a general overview of HACCP.)

An assessment of the hazards associated with the preparation/ processing/storage of ready-to-eat meat products should be conducted. Then, a determination of the critical control points to eliminate or reduce hazards should be done.

Critical control points (CCP) in the processing of each lot of finished product should be monitored to ensure compliance with established procedures. Firms should take steps to adequately monitor the CCP to ensure uniform control over Listeria monocytogenes contamination which may occur upstream in the process.

1. General Requirements

*Specifications should be established for raw materials to control the microbiological load of the ingredients.

*Processing should be supervised by technically competent personnel. All steps in the production process, including packaging, should be performed without unnecessary delay.

*Processing should be conducted according to written formulae and procedures, established by recognized processing authority, in accordance with good manufacturing practices and regulatory requirements.

*All packaging material should be stored in a clean and sanitary manner. Only packaging material required for immediate use should be kept in the packaging or filling area. Packaging material should be sound and should provide appropriate protection from contamination.

*All equipment which has been in contact with raw or contaminated materials should be thoroughly cleaned and disinfected prior to being used for ready-to-eat products.

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*Research has shown that Listeria monocytogenes grows twice as fast at 10°C as at 5°C. Therefore, the meat processing environment must be kept as cold as practical. Adequate capacity and sufficent air circulation to maintain desired temperature and control humidity under all conditions must be provided. All refrigerated spaces should be equipped with temperature measuring or recording devices.

2. Cross-Contamination

*Returned products should not be used unless they have not left the processor's control. In those cases, returned products should always be handled as raw product.

*Bacon is not a ready-to-eat product. Separate the slicing operation physically or by operating practice. Employees in the bacon operation should change outer clothing, wash hands or change gloves before returning to ready-to-eat meat products.

*Some processes cannot be kept dry, for example mold knocking, shower areas, removal from cook-in-bag films. Isolate these processes, contain moisture, clean frequently and sanitize if possible. Traffic should be minimized in this area.

3. Quality Assurance

*All thermal processes should have been designed and validated by a recognized processing authority to ensure the reduction of contamination to the required level and the elimination of Listeria monocytogenes.

*Permanent, legible and dated records of pertinent processing and production details should be kept concerning each lot. These records should be retained for a period that exceeds the shelf life of the product or as required by regulatory authorities.

*It is desirable that each establishment has access to laboratory control of the products processed. Laboratory procedures used should follow approved standard methods (or other approved equivalents) in order that the results may be readily interpreted.

.../10

4. Specific Operations of Concern

Cooked products handled/processed prior to final packaging (roast beef, corned beef)

*Where possible, the product should be cooked in its final packaging to avoid further contamination

*Trimming, slicing and cutting for repackaging after cooking requires exceptional attention to sanitation and prevention of cross-contamination by Listeria monocytogenes

*Repackaging requires a sanitary working environment, washing bagged product before opening, sanitized utensils, clean clothing and frequently sanitized gloves.

Frankfurters and other link products

*Since Listeria monocytogenes is very salt tolerant, brine chillers may harbour Listeria monocytogenes and contaminate casings and product surfaces. Routine replacement of brine should be instituted.

*Peeler operator protective garments and gloves may be a source of contamination. These garments should be changed frequently and, if not disposable, should be thoroughly cleaned, sanitized and dried prior to use.

*All product that touches floors or other non-product contact surfaces is to be thrown out.

*Accumulated meat scraps, grease and juices should be frequently removed from equipment.

Luncheon Meats

*Contamination of product during the removal of cooked product from casings or molds should be avoided.

*Product on trucks and trollies should be protected from contamination via splash from floors and wheels, as Listeria monocytogenes is frequently isolated from floors.

*Slicing equipment should be kept as dry as possible, free of scraps and juices.

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E. RECALL PROCEDURE

*A procedure to permit the complete, rapid recall of any lot of the finished product from the market should be established following the product recall procedures as outlined by the Health Protection Branch (see Appendix C).

.../12

F. SUGGESTED REFERENCES ON CONTROL OF LISTERIA

1. American Meat Institute. 1988. Interim guideline: Microbial control during production of ready-to-eat meat products. Controlling the incidence of Listeria monocytogenes. Second edition.

2. Messina, M.C. et al. 1988. The effect of liquid smoke on Listeria monocytogenes. J. Food Protection. 51: 629-631.

3. Moore, D. 1988. How to control Listeria in dairy plants. Modern Dairy. December 1988.

Revised - March 2, 1989/bb

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Appendix A

Code of Practice -
General Principles of Food Hygiene
for use by the Food Industry in Canada

Appendix B

General Overview of HACCP

HACCP: MAKING THE SYSTEM WORK

HACCP first came to light in the sixties, in support of the U.S. effort to send men into space. But it remains as contemporary as the latest food safety concern, and is a procedure processors should be familiar with.

CHUCK HABERSTROH
Editor-in-Chief

HACCP (usually pronounced "hassap") is an acronym for Hazard Analysis/Critical Control Points. It's nothing new—though it is a philosophy and a methodology that has not achieved the currency it should. It is, fortunately, undergoing a renaissance of attention. In fact, this past February the Food Processors Institute held a two-day seminar that brought together some of the most knowledgeable people on HACCP in the U.S. And when, late last year, *Food Engineering* co-sponsored a two-day executive briefing on microbiological safety in the food industry, the concept of HACCP played an important part in the discussions.

At its simplest, HACCP is, as we called it on this month's cover, preemptive quality control. That's because the rationale in establishing a HACCP system of quality control is to design and check the process so that the final product is not contaminated—not test for contamination after it may have taken place. HACCP pushes Q/C responsibility upstream, to a point even before the manufacturing process begins—all the way back to the supplier. And a manufacturer may even go so far as to require that all suppliers also run according to a HACCP philosophy.

Out of the space age

To provide a specific context for HACCP, let's take a look at its roots. Robert Wooden, manager of product safety and regulatory affairs at Pillsbury (Minneapolis, MN), describes how his company went about creating the first HACCP program. "[Pillsbury] encountered problems when we were asked to design and manufacture the first space foods for the Mercury flights. As we moved on to Gemini with its more complex foods and longer flights, the problems were magnified. By the time Apollo landed on the moon, HACCP was developed. Within two years of that first moon landing, HACCP was in commercial use in the manufacture of consumer foods at Pillsbury."

The challenge: "To come as close to one hundred percent assurance as possible that the food products...for space use would not be contaminated with pathogens...that might result in a catastrophic mission."

The first roadblock: "Using standard methods of quality control there was absolutely no way we could be assured that there wouldn't be a problem."

The second roadblock: "The amount of testing that we had to do to attempt to come close to a reasonable decision point as to whether a food was acceptable was extremely high."

The question: "If to produce a product with a high level of assurance of safety we had to do a great deal of destructive testing, how much were we missing in the way of safety issues in our plants by only testing primarily the end product and occasionally testing raw materials?"

The answer: "We concluded...that the only way we could succeed would be to have control over the process, the raw materials, the environment and people-beginning as early in the system as we possibly could....For all practical purposes, if done right it would not require any testing of the finished packaged material other than for monitoring purposes."

And so, HACCP was born.

Total approach, not piecemeal policing

The HACCP system must be an integrated approach to the whole processing procedure. If it is spotty, nothing will be accomplished. It is necessary to rigorously set it up, and rigorously follow it.

Wooden notes that the "system can be used to control any area that could contribute to a hazardous situation, whether it be contaminants, pathogenic microorganisms, raw materials, a process, use directions for the consumer, or storage condition. The hazard analysis portion is the identification of sensitive ingredients and sensitive areas in the processing of the food or otherwise. From these we identify the critical control points that must be monitored to assure safety of the product. The critical control points are those areas in the chain of food production from raw materials to finished product where the loss of control could result in an unacceptable food safety risk."

Raw materials

When Wooden refers above to "any area that could contribute to a hazardous situation," he is referring principally to the four he noted earlier:

- Raw materials,
- The process itself (e.g., equipment, monitoring devices),
- The process environment (e.g., workers, plant, grounds), and
- Distribution and consumer abuse.

Let's take raw materials. This aspect involves at least two crucial phases. The first is establishing hazard categories for various ingredients vis-a-vis various microbiological contaminants, like Salmonella. The hazard

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Hazard analysis (microbiological)

[illegible] Refrigerated Dip

Item	RISK CHARACTERISTICS Sensitive Ingredient	 Microbes Not Destroyed	 Abuse Potential	HAZARD CATEGORY
Product				
Refrigerated Dip	+	+	+	II
Ingredients				
Raw Celery	+	+	0	III
Dried Mushrooms	+	0	+	II
Soft-Ripened Cheese	+	+	+	II
Water	+	0	0	IV
Salt	0	0	0	V

Hazard analysis is essentially a two-step process, illustrated here with regard to a company considering the manufacture of a new "fresh" refrigerated party dip where ingredients will be as little processed as possible.

First, there is the matter of determining the ingredients' and finished product's hazard characteristics, and then identifying the appropriate hazard category.

First, let's take a look at some definitions, courtesy of Dr. Donald Corlett, corporate scientist, thermal processing and microbiological safety at the Del Monte Research Center (Walnut Creek, CA).

RISK ASSESSMENT: A yes/no evaluation of a product and its ingredients according to their hazard characteristics, using "+" for yes and "0" for no.

–*Hazard Characteristics*:

- A: Sensitive ingredient or ingredients.
- B: The manufacturing process does not contain a controlled processing step that effectively destroys harmful bacteria.
- C: There is substantial potential for microbiological abuse in distribution or in consumer handling that could render the product harmful when consumed.

HAZARD CATEGORY: Ranking based on risk assessment.

–*Categories:*

- I: A special category that applies to nonsterile products designed and intended for consumption by infants, the aged, or the infirm.
- II: Food products subject to all three general hazard characteristics (+ + +).
- III: Food products subject to two general hazard characteristics (+ 0 +, + + 0, 0 + +).
- IV: Food products subject to one of the general hazard characteristics (+ 00, 0 + 0, 00 +).
- V: Food products subject to none of the general hazard characteristics (000).

It is easy to see that the refrigerated dip product illustrated on the left has a high degree of risk:

- Sensitive ingredients,
- No kill step, and
- Real potential for consumer abuse.

Special concern needs to be focused on the mushrooms and cheese—they need to be tested or, preferably, gotten from a supplier who uses HACCP. The celery and mushrooms should also be tested for pesticides and inspected for foreign matter. All this, plus microbial tolerances, can be specified to the supplier.

There is also the possibility, Dr. Corlett notes, of modifying some of the process steps (e.g., using canned mushrooms). These would result in a less "fresh" product, but a much less potentially hazardous one.

HACCP

category essentially establishes the level of risk associated with a particular ingredient or product. So, for example, fish breading/batter mix might be a category III for Salmonella (containing less than 30% Salmonella-supporting components); while soy protein might be a category II (potentially higher risk of Salmonella).

Providing all these designations is an arduous task. But the essence of a HACCP program, and the reason why once in place you can be confident of its reliability, is that it is precise and *total*.

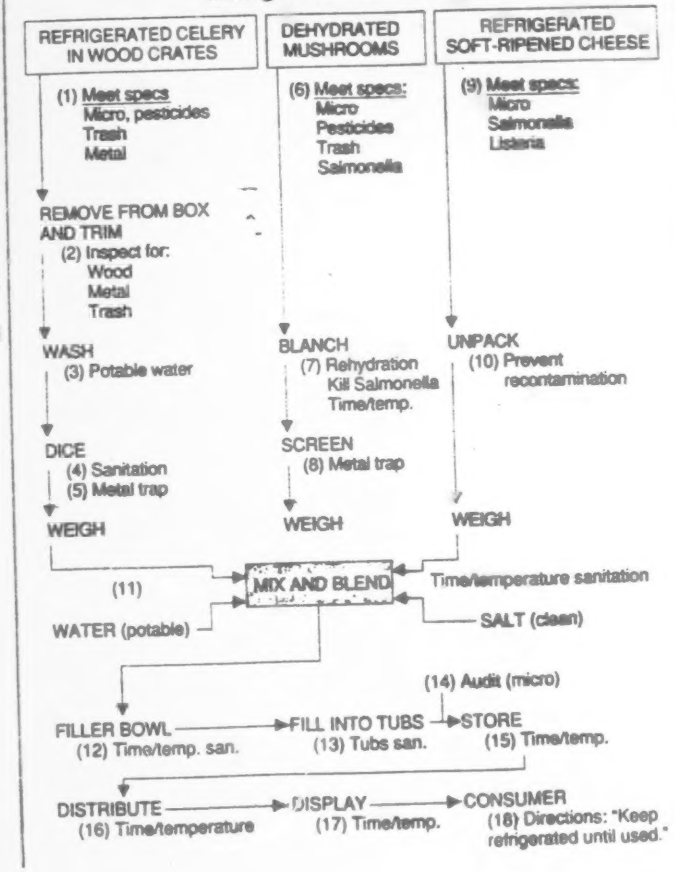
The second crucial phase of controlling raw materials is using those hazard categories to establish specs for suppliers, while at the same time reviewing supplier procedures to be certain they can meet the specs on a guaranteed basis.

How thorough does that need to be? Well, one processor's forms for a supplier evaluation run 12 pages, covering things like the supplier's incoming materials controls and tests, process controls, brands and aperture sizes of metal detectors, GMPs, and building maintenance, just to name a very few.

After risk assessment, as illustrated on the previous page, the next step is to make a flow diagram of the process and establish the critical control points on it. These are shown by the numbers in parentheses. Normally, the critical control points will have to do with:

- **Raw materials and ingredients,**
- **Preservative factors (pH, Aw, etc.),**
- **Time/temperature,**
- **Sanitation,**
- **Preventing cross-contamination,**
- **Food handling/employee hygiene, and**
- **Special controls.**

Refrigerated snack dip


REFRIGERATED CELERY IN WOOD CRATES
(1) Meet specs
Micro, pesticides
Trash
Metal
REMOVE FROM BOX AND TRIM
(2) Inspect for:
Wood
Metal
Trash
WASH
(3) Potable water
DICE
(4) Sanitation
(5) Metal trap
WEIGH
DEHYDRATED MUSHROOMS
(6) Meet specs:
Micro
Pesticides
Trash
Salmonella
BLANCH
(7) Rehydration
Kill Salmonella
Time/temp.
SCREEN
(8) Metal trap
WEIGH
REFRIGERATED SOFT-RIPENED CHEESE
(9) Meet specs:
Micro
Salmonella
Listeria
UNPACK
(10) Prevent recontamination
WEIGH
(11)
MIX AND BLEND
Time/temperature sanitation
WATER (potable)
SALT (clean)
FILLER BOWL
(12) Time/temp. san.
FILL INTO TUBS
(13) Tubs san.
(14) Audit (micro)
STORE
(15) Time/temp.
DISTRIBUTE
(16) Time/temperature
DISPLAY
(17) Time/temp.
CONSUMER
(18) Directions: "Keep refrigerated until used."

In other words, the processor is no less ugh with the supplier than he would be vith one of his own plants. The supplier should get a report card. Some companies do an analysis as frequently as every six months for all their suppliers. As one manufacturer noted, "That is how you get to be 'preferred.' "

The process

In the plant, the processor should have a food safety analysis for each different product. This analysis consists of:

- A list of all ingredients in the product (including each ingredient's number, percent used in product, hazard category, and specific hazard contribution to that product);
- An evaluation of those production safety requirements (equipment, measurements, and tests) that are critical to the safety of the product; and
- An evaluation of distribution requirements, including shelf life at various storage temperatures, critical humidity, and potential hazards from consumer errors in handling, preparation, or storage.

This is done for each product where there is a formula or process variation, and is signed off on by the appropriate product development scientists, processing engineers, packaging scientists, and the Q/A people.

Doing it effectively

There are some basics in getting a handle on HACCP, and one of them is to assign a single individual the responsibility for getting it done. The danger of losing control of an effective HACCP procedure often comes from the fragmentation of attention that comes with the fragmentation of responsibility. There must be consistency.

In the same way that there should be one person in charge, his or her responsibility should be embodied in a separate Product Safety Office that deals with the whole panoply of things that we have seen go to make up HACCP—e.g., procurement, reliability reviews, and proper safety controls.

The Product Safety Office in turn should create and manage a formal review committee that reflects the technical and business disciplines that enter into HACCP decisions—microbiology, engineering, product

Attribute sampling

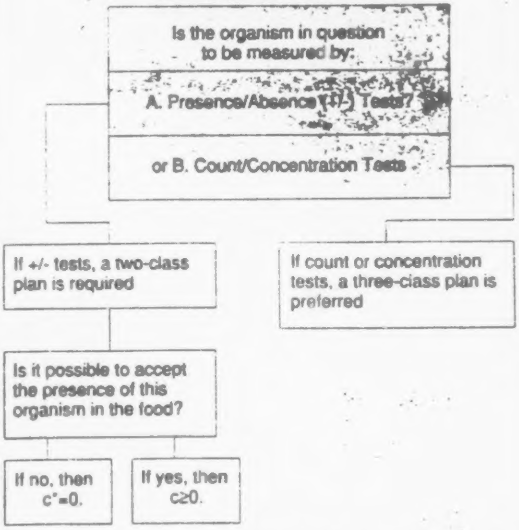
Attribute sampling of lots is important to HACCP procedures, and needs to be used in one of two situations:

- With ingredient lots where microbiological, chemical or physical conditions are unknown or require testing to approve for processing, or
- Troubleshooting finished lots when the circumstances of continuous monitoring are out of control or unknown (i.e., where other critical control points may have failed).

Two types of sampling plans are recommended:

- Two-class plan: A simple go/no-go, acceptable/non-acceptable procedure, generally using the symbols n(number of sample units per lot), c(maximum allowable number of sample units yielding an unsatisfactory result, and m(microbiological limit);
- Three-class plan: Classifies counts as acceptable, marginal, and unacceptable, using the symbols n and c, but where m = microbiological limit (marginally acceptable), and M = microbiological limit (unacceptable).

Sampling plan decision tree


Is the organism in question to be measured by:
A. Presence/Absence (+/-) Tests?
or B. Count/Concentration Tests
If +/- tests, a two-class plan is required
If count or concentration tests, a three-class plan is preferred
Is it possible to accept the presence of this organism in the food?
If no, then c*=0.
If yes, then c≥0.

*c= maximum allowable number of sample units yielding an unsatisfactory result.

development, legal, and marketing.

Next – wherever feasible – the one committee should review the procedures of all manufacturing divisions, whether they are making ice cream or pizza. Again, what you want is consistency. In the same way, lab people should be adequately trained; not so much to insure that they can perform certain tests, but to make sure that whoever is running the test in whatever lab at whatever division and with whatever length of service in the company, they are always using the same methodology.

Last but not least, one of the most important parts of establishing a HACCP system is creating diagrams of each current manufacturing line. This may be a simple box diagram, or it may be more complicated. But it must contain all the current operations in each of the lines. The reason is that this helps to define the interrelations between one part of the process and another, which in turn makes establishing proper critical control points much more certain.

There is a concomitant rule that goes along with the production of flow diagrams: *Any and all changes in any part of the process must be cleared with the Product Safety Office before they take place.*

Setting the critical control points

Dr. Donald Corlett, corporate scientist for thermal processing and microbiological safety at the Del Monte Research Center in Walnut Creek, CA, notes that establishing critical control points in a HACCP system for microbiological hazards requires a complete understanding of the dangerous organism's profile, in particular those factors that influence its survival in food (e.g., sources of contamination, growth temperature range, resistance to acidity).

From these and other factors flow the specifications that are the keys to preventing the hazards and which become parts of the

Suggested sampling plans

[illegible] on degree of health hazard and conditions of use)

	Conditions in which the food is expected to be handled and consumed after sampling, in the usual course of events.*		
Degree of concern relative to utility and health hazard	Conditions reduce degree of concern	Conditions cause no change in concern	[illegible]
NO DIRECT HEALTH HAZARD	Increase Shelf Life	No Change	[illegible]
Utility (e.g., shelf life and spoilage)	Case 1 3-class n**=5, c**=3	Case 2 3-class n=5, c=2	[illegible]
HEALTH HAZARD	Reduce Hazard	No Change	[illegible]
Low, indirect (indicator organisms)	Case 4 3-class n=5, c=3	Case 5 3-class n=5, c=2	[illegible]
Moderate, direct, limited spread	Case 7 3-class n=5, c=2	Case 8 3-class n=5, c=1	[illegible]
Moderate, direct, potentially extensive spread	Case 10 2-class n=5, c=0	Case 11 2-class n=10, c=0	[illegible]
Severe, direct	Case 13 2-class n=15, c=0	Case 14 2-class n=30, c=0	[illegible]

*More stringent sampling plans would generally be used for sensitive foods destined for susceptible populations.

**n=number of sample units per lot
c=maximum allowable number of sample units yielding an unsatisfactory result

Source: ICMSF, 1986

HACCP

What began at Pillsbury as a no-defects system to create food for the astronauts (top), is today producing the new wave of consumer products (bottom). Source: Pillsbury

system of critical control points on the processing flow diagrams and on the plant floor. They also become the monitoring and testing limits that determine whether a critical control point is in spec or not. And any specification for a critical control point should have five major components:

- The control point and its parameters,
- The monitoring procedure,
- The monitoring frequency,
- The decision criteria for acceptable and unacceptable controi, and
- The action to be taken if control is unacceptable.

With respect to monitoring, Corlett notes, "A critical control point is intended to prevent a catastrophic event, and from the monitoring standpoint, a failure in a critical control point is a critical defect." Because of this, Corlett favors "using HACCP systems for only direct hazards, and very sparingly for those non-hazardous situations which are of serious regulatory, consumer, or economic consequence." Some might disagree with the second part of Corlett's statement, feeling that serious regulatory, consumer, or economic consequences need to be addressed by HACCP as much as the microbiological consequences. Corlett's perspective, however, is that "*too much* monitoring effort at the critical defect level dilutes out the detection of potential hazards. Less important monitoring should be part of a standard quality program."

As to the type of monitoring used, Corlett believes that "critical control points ideally require continuous inspection. However, from a practical standpoint this is not always possible. For this reason, the *design* of HACCP systems is a most important feature in developing monitoring systems, and judgment and discretion are of key importance in designing the critical control point and its monitoring program."

Continuous monitoring

Where the design of the HACCP system allows continuous monitoring procedures, it is important to know the expected variation of the equipment, to ensure that the critical control point does not go out of control. This should be done, Corlett notes emphatically, by testing the operation of the equipment before use. For example, destroying Salmonella in meat patties takes 150°F for one minute. If patty temperatures in the oven will vary by five degrees either way, the operating limits for patty temperatures would be: min. = 150°, max. = 160°, target = 155°. There are, however, actually three critical control points that need monitoring in this situation: temp. = 150°F; time = one minute or more; patty thickness = not to exceed standard thickness. Each has its attendant technology, and each one of those technologies requires continuous monitoring.

One further note: The use of continuous inspection will vary with the type of preservation technology. For example, if the same product could be frozen, canned, or refrigerated, the controlling step for microorganisms would change with each.

Attribute sampling

"Attribute sampling is the only way," outlines Corlett, "to test ingredients with an unknown history or to determine if they are acceptable for a particular product. Attribute sampling is also used to test held lots where other critical control points have failed."

Sampling should be governed by microbiological criteria, and a criterion should include:

- A description of the food or ingredient,
- A description of the contaminant of concern,
- The analytical method to be used for the sampling,
- The sampling plan, and
- The microbiological limits considered appropriate to the food and commensurate with the sampling plan.

The accompanying sampling plan decision tree (p. 75) and suggested sampling plans (p. 78) will give some idea of what is involved in setting up the all-important sampling plan component of the criterion. In general, there are two-class and three-class sampling plans. The first is a simple acceptable/non-acceptable plan used for "severe, direct" and "moderate, direct, potentially extensive" hazards. Three-class, on the other hand, are more flexible, and are used in those situations where a certain greater tolerance of contamination is possible in the ingredient or product.

To sum up

We have here only been able to touch the surface of HACCP. But there are a few things to keep in mind. For one, it is a total system and a particular mindset about manufacturing: It is *pro*-active rather than *re*-active. Second, it is not easy – but neither are the potential lawsuits, prosecutions, and recalls that a company can be exposing itself to if HACCP is not part of its thinking. Third, it integrates quite well with existing Q/A and Q/C procedures, and reflects much of what is already current in GMPs.

Last, as Robert Wooden notes: It works.

Appendix C

Food Product Recall

FOOD PRODUCT RECALL

1. Background and Objectives

Recall is an effective method of removing or correcting violative food products that may represent a health hazard to the consumer or user. It is an action taken by a manufacturer, distributor, or importer to carry out their responsibility to protect the public health and well-being.

2. Definitions

(a) "Recall" with respect to a food product, means a firm's removal from further sale or use, or correction, of a marketed product that violates legislation.

The definition of "Recall" does not include a "food product withdrawal" or a "stock recovery".

(b) "Product withdrawal" means a firm's removal from further sale or use, or correction of a marketed food product that does not violate federal legislation. It is not considered to be a recall.

(c) "Stock recovery" means a firm's removal or correction of a food product that has not been marketed or that has not left the direct control of the firm. It is not considered to be a recall.

(d) "Recall classification" is the numerical designation, i.e. Class I, Class II or Class III, assigned to a particular food product recall to indicate the relative degree of health hazard presented by the food product being recalled.

(1) Class I is a situation in which there is a reasonable probability that the use of a violative food product will cause serious adverse health consequences or death.

(2) Class II is a situation in which the use of a violative food product may cause temporary adverse health consequences or where the probability of serious advserse health consequences is remote.

(3) Class III is a situation in which the use of a violative food product is not likely to cause any adverse health consequences.

5. CLEAN-UP PROTOCOL

CLEAN-UP PROTOCOL

INTRODUCTION

The meat industry in Canada is a large and diverse one, with great variations in the sizes of plants and the products that they produce. Some plants are highly specialized to a single type of process, whereas others are multi-purpose operations. In this discussion, however, the common factors in the industry are more important than the differences. One important common factor is that every meat plant absolutely requires good hygiene.

Some ready-to-eat meat products provide an almost ideal medium for bacterial growth. The high moisture content, neutral pH and abundant nutrients found there are well suited for many types of bacteria, including some species that cause illness in humans. Some of these organisms are well known in the meat trade, such as Salmonella and Staphylococcus. Other organisms, not previously known to cause illness, are now becoming a concern in meat products, eg. Listeria monocytogenes and Escherichia coli 0157/H7. These new hazards pose a challenge for industry and regulators alike. Fortunately though, they can be controlled utilizing the same techniques as with other bacteria; effective clean-up and sanitizing.

CLEANING

As previously indicated in the GMP section, every manufacturer should have a comprehensive written cleaning and sanitizing program for its operation. This program should ensure that all food handling areas are adequately cleaned and sanitized.

A typical cleaning process will involve as many as six separate steps:

1. Pre-Cleaning

   Preparation of area and equipment for cleaning. Involves steps such as removal of all product from area, protection of sensitive components and packaging materials from water, removal by hand or squeegee of meat scraps, etc.

2. Pre-Rinse

   A rinsing with water to remove remaining large pieces of loose soil.

3. Cleaning

   Treatment of surfaces with an appropriate detergent to remove soil.

4. Rinse

   A rinsing with water to remove all soil and detergent.

5. Sanitizing

   Application of chemicals and/or heat to destroy most micro-organisms on surface.

6. Post-Rinse

   A final rinse with water to remove sanitizing agent. This step is not applicable or recommended in all situations.

The specifics of the cleaning program will vary to individual circumstances and the program must be designed to meet the needs of each individual operation. Each of the six steps must be customized to provide the best possible results.

This customizing requires a detailed examination of the following factors:

- what are the products being produced, and what is the soil that results;
- how is the product produced, and on what equipment;
- what materials are used in the construction of the equipment;
- what is the structure and layout of the plant. What power, water, steam is available;
- what is the quality and nature of the water.

These factors will ultimately determine what type of cleaning equipment, cleaning chemicals, sanitizing agents and overall program are best suited to that application.

CREATING A PROGRAM

Ideally, the program should be created after consultation with production management, plant engineers, cleaning supply representatives and local inspectors. The program may also be written by a consultant or other competent person. In any event, the program should consider several key points:

- The majority of the soil occurring in meat plants is protein and fat. These are both insoluble in water and are soluble in alkaline cleaning solutions. In addition, proteins are soluble in acidic cleaning solutions. Enzymes are sometimes used as ingredients in detergent and are effective in helping to remove fats and proteins.

- Temperature is a critical factor. Although fats are removed much more easily when cleaning solutions are at/or near the melting point of the fat; $70^{\circ}C$ ($158^{\circ}F$) in some cases, these temperatures will coagulate any proteins present making them much more difficult to remove. Detergent solutions utilize a variety of ingredients to remove and disperse soil and don't require high temperature so excess heat is ineffective and wasteful. Water temperatures in the range of 45° to $50^{\circ}C$ are usually sufficient for cleaning.

- The majority of equipment in use in meat plants, including that used to manufacture ready-to-eat meats, is unsuited to automated cleaning systems. The cleaning program will probably be designed around a labour intensive manual system. Although manual systems are totally effective when carried out properly, they can be rendered ineffective through human error or carelessness. As such, great diligence is required to ensure that the clean-up has been properly conducted. The effectiveness of the program should be monitored by supervisory and quality control staff.

- Automated clean-in-place (C.I.P.) systems may be suited to some operations and equipment, such as blenders, smokehouses, or emulsion pipes. Separate C.I.P. systems should be used for raw and cooked product operations.

- The physical design of the equipment may pose specific problems in clean-up. Dead-spots or niches are often present. These can prove to be inaccessible for cleaning, and may harbour large numbers of micro-organisms. Small amounts of trapped soil, with accumulated moisture there since the last clean-up are ideal media for such growth. This is especially troubling in meat plants where the equipment is usually located within a refrigereated room. These low temperatures will normally inhibit the growth of most bacteria, but will permit the growth of Listeria. The organisms that may grow there can become dislodged at any time resulting in a seemingly random contamination of that product with Listeria.

  All equipment should be examined for potential niches or dead-spots. Typical sites are improperly welded surfaces, bolted metal to metal surfaces, unsealed hollow structures, conveyors, protective shields, improperly applied caulking and drive motor compartments. These should be eliminated wherever possible. Alternative measures would include alteration of the equipment to prevent collection of soil and water, or alteration to provide adequate drainage and complete drying. Also, these high risk areas can be specifically identified in the written program and given special attention during cleaning.

- For some accepted sanitizers a post-rinse may not be appropriate in all situations. Some sanitizers are permitted to be left on food contact surfaces at certain concentrations without rinsing provided they are used in keeping with the instructions outlined on the label. (See Appendices I and II).

  If higher sanitizer strengths are desired, the equipment must be rinsed prior to use. The rinse water must be potable, and the equipment should be allowed to dry completely before use.

- The equipment being sanitized must be clean. Residues of meat and fat will inactivate most sanitizers.

- If the equipment is not used within 24 hours of sanitizing, it will need to be sanitized again prior to use.

- If a mid-shift clean-up is desired, all of the steps of a normal clean-up will have to be followed. A simple mid-shift rinse of equipment to remove accumulated soil is not recommended. Unless the equipment and environment is able to dry completely prior to the resumption of processing, the residual moisture will contribute to the growth of Listeria. It is also not effective to simply rinse and then sanitize the equipment, as soil residues will decrease the effectiveness of most sanitizers.

- The cleaning and sanitizing compounds used must be compatible with the materials used in the construction of the equipment. For example, strongly alkaline detergents can corrode aluminum, and chlorine from hypochlorite solutions is corrosive to most metals, especially stainless steel. Iodophors stain some plastics, and may impart a taste to the food product as a result. No single product is perfect for all applications.

- Structures and facilities in food handling areas will need to be cleaned, in addition to the food-handling equipment. Listeria has been found on numerous non-contact surfaces in meat plants, including:

  - floors
  - walls
  - ceilings
  - drains
  - cleaning brushes and cloths
  - hand towel dispensers
  - compressed air

  The cleaning program should include provisions to clean and sanitize such non-contact surfaces. Once again be aware of areas that may trap moisture and serve to harbour bacteria, such as overhead light fixtures.

- The physical layout of the plant, and operations that occur in adjacent areas will need to be considered. Cleaning and sanitizing operations must be separated in time and space from food production. (See GMP section for further guidance).

- The materials used on structure and facilities in food handling areas must be considered. These too may prove incompatible with cleaning and sanitizing agents.

- The firm should have adequate steam and/or hot water at its disposal to adequately carry out the intended cleaning program. Ample potable water is also essential. The microbiological quality of the water used in processing and cleaning should be monitored by the Quality Control Department and meet provincial or federal potable water standards.

- The hardness of the water used for cleaning must be determined prior to selection of cleaning chemicals. The relative proportions of the ingredients in the detergent must be compatible with the mineral content of the water.

- Once initiated, the cleaning program should be validated through microbiological testing to ensure that it is effective in eliminating Listeria and indicator organisms. The program should also be regularly monitored with microbiological testing and records should be kept. Changes in processing or the cleaning program would necessitate a re-validation of the program.

DETERGENT AND SANITIZERS

The ideal detergent or sanitizer for the meat industry, of course, does not exist. Plant management must balance all considerations when choosing their chemicals to find the most appropriate ones.

To be useful in a meat plant, a detergent must have the following properties:

- be soluble in water;

- be easily applied to contact surfaces;

- be able to thoroughly wet the surface - by reducing the surface tension of water. This will assist the penetration of the cleaning agent into the soil;

- be able to disperse and suspend the soil - to inhibit it from re-depositing on surfaces;
- be able to emulsify fats - that is break the fat into small droplets that are kept suspended in solution;
- be able to saponify fats - that is the chemical conversion of fats to soluble soaps that are easily rinsed;
- be able to dissolve proteins;
- be easily rinseable.

These properties are determined by the addition of specific components to the detergent, such as alkalis, acids, phosphates, sequestrants and surfactants. A detailed discussion of these ingredients would fill a text-book and is not appropriate here. Cleaning supply companies are the best source of information on the types of detergents best suited to a given application.

Sanitizers may be heat or chemical agents, and can be divided into the following broad categories:

1. Heat - eg. steam
2. Chlorine Compounds - eg. Hypochlorites
3. Iodine Compounds
4. Quaternary Ammonium Compounds
5. Acid-Anionics

Each of these sanitizers has advantages and disadvantages. The sanitizer used must be appropriate for Listeria monocytogenes, for the equipment on which it is applied, and must also be compatible with the detergent used. See Appendix II for a list of their relative properties.

SAFETY

Use care when handling all cleaning and sanitizing compounds, and follow all manufacturers instructions for storage, mixing and use.

- Wear safety glasses, boots, gloves and aprons when working with undiluted chemicals.
- Mix the chemicals with water carefully. Add the chemical to water slowly and agitate gently.
- Chlorinated compounds can react with hot water, ammonia, alkalies and acids. Dangerous gases can result. Don't mix chlorinated compounds with anything not recommended on the label.
- Do not mix acid and alkali products.
- Store chemicals in a clean dry area. If special storage instructions are given for any product, ensure that they are followed.
- Chemical storage areas should be kept locked and access to them limited.
- Do not store cleaning and disinfection chemicals near foods.
- Use only chemical that have been approved by the appropriate inspection agencies.

WRITTEN PROGRAM

Once the cleaning program has been designed it is imperative that it be recorded. The written program will serve as a reference document for the training and daily function of sanitation personnel. It will also serve as a reference for management and regulators against which the daily clean-up can be measured.

The written program should specify the cleaning and sanitation to be performed in every food-handling area. A separate program should be created for different processing areas or lines, as required.

Each program should specify:

- The area/line, etc. to be cleaned, and the frequency of cleaning.
- The equipment to be cleaned. Specific instructions on special procedures, eg "conveyor on X-22 line should be left running" should be included.
- The cleaning equipment to be used.
- The cleaning and sanitizing chemicals to be used. Specific brand names should be listed. Dilution ratio, special mixing instructions, water temperatures should be included.
- The method of application of the solutions. If special problem areas exist, note them so they are given specific attention. The contact time necessary for cleaning should be listed.
- Rinsing instructions.
- Sanitizing instructions, including specific brand names, dilution ratio and contact time.
- Post-rinse instructions, if appropriate.
- Safety instructions for the use of these chemicals should be included.

A suggested format for written cleaning programs is as follows. This is an example for your information and guidance only.

Cleaning Program - Sliced Cooked Meats Packaging Area

This program is to be conducted each day at the conclusion of the afternoon production shift. Employees shall wear rubber gloves and eye protection while using alkaline cleaners.

1. **Production staff are to remove all food products from area. Large scraps of meat are to be removed by hand or squeegee.**

2. **Pre-rinse the packaging machines and conveyor with potable water at 250 - 300 psi and 45 - 50°C. Rinse from top-down and in a repeated pattern to minimize water usage. Remove remaining meat scraps with rinse.**

3. Add 1 1/2 gallons of XYZ brand 123 Alkaline foam cleaner to 25 gallons of cold water in 100 gallon wash tank; agitate while adding. Slowly add 75 gallons of hot water to bring temperature to 50°C.

   Adjust chemical and air controls to produce a medium texture foam. Settings of X litres per minute, and Y psi are recommended.

   Spray on all equipment in a thin layer. Leave on for seven to ten minutes. Ensure that conveyor is left running during spraying.

4. Rinse with potable water at 250 - 300 psi and 45 - 50°C. Rinse from top-down and in a repeated pattern to minimize water usage.

5. Sanitize with XYZ brand Quat sanitizer. Add 5 oz. to 20 gallons of water to achieve a final concentration of 200 ppm. Spray on all equipment surfaces. Ensure that conveyor is left on. Do not rinse off.

Suggested References on Control of Listeria

1. Lopes, J.A. 1986, Evaluation of Dairy and Food Plant Sanitizers Against *Salmonella typhimurium* and *Listeria monocytogenes*. J. Dairy Science 69:2791-2796.

2. Brackett, R.E. 1987, Antimicrobial Effect of Chlorine on *Listeria monocytogenes*. J. Food Protection 50:999-1003.

3. El-Kest, S.E., and Marth, E.K. 1988, Inactivation of *Listeria monocytogenes* by Chlorine. J. Food Protection 51:520-524.

4. El-Kest, S.E., and Marth, E.K. 1988, Temperature, pH, and Strain of Pathogen as Factors Affecting Inactivation of *Listeria monocytogenes* by Chlorine. J. Food Protection 51:622-625.

5. Messina, M.C. et al. 1988, The effect of Liquid Smoke on *Listeria monocytogenes*. J. Food Protection 51:629-631.

APPENDIX I

GUIDELINES FOR THE USE OF CLEANING AND SANITIZING AGENTS IN FOOD PROCESSING ESTABLISHMENTS

The evaluations of cleaning and sanitizing agents used in food processing establishments are carried out by the Agri-Food Safety Division, Hygienic Environment program on an individual basis in conjunction with the Division of Chemical Evaluation, Bureau of Chemical Safety, Food Directorate of Health Protection Branch. The main purpose of such evaluations is to minimize the possibility of food contamination resulting from the use of these substances. Product information is submitted on a voluntary, confidential basis by industry. The product composition, levels and areas of use, labelling, etc., are all taken into consideration. Any comments, precautions or restrictions which apply to its use are provided to the manufacturer, and are incorporated in the accepted labels directions for use.

General guidelines regarding the use of cleaning and sanitizing agents are as follows for those accepted agents:

Products used to *clean* food contact surfaces in food plants should, *without exception*, be followed by a *thorough* rinse with potable water. Following this cleaning and rinsing procedure, the use of a sanitizing agent is recommended for the purpose of reducing the microbial load on the surface. The use of such a product is usually followed by a potable water rinse; however, in order to optimize the effectiveness of these sanitizers, this final rinse (if required) is often delayed until just prior to the re-use of the equipment.

Certain products are considered to be acceptable for use as sanitizing agents without a final potable water rinse, and, in recent years, the demand for such products has grown. Based on the available data, products considered to be acceptable for use as sanitizing agents on food contact surfaces without a final potable water rinse include:

a) *Certain* chlorine-releasing agents at a maximum use concentration of 200 ppm available chlorine;

b) *Certain* quaternary ammonium compounds at a maximum use concentration of 200 ppm available active ingredient;

c) *Certain* iodophors at a maximum use of concentration of 25 ppm available iodine.

It should be emphasized that this no-rinse status would not necessarily apply to all chlorine-releasing compounds, all quaternary ammonium compounds, or all iodophors. In addition, the no-rinse status may not be restricted to these types of products. The acceptability of using a specific sanitizing agent without a final potable water rinse can only be determined after an individual product evaluation.

If the sanitizing agent itself is found to be acceptable for no-rinse applications, such use would still be subject to the following requirements:

(i) The food contact surface must be constructed of a hard non-porous material.

(ii) The food contact surface must have been previously cleaned. (A final potable water rinse should still follow the cleaning step).

(iii) The food contact surface must be effectively drained to remove, as far as is possible, all residues of the sanitizing agent.

If any one of these requirements cannot be guaranteed, then a final potable water rinse would be required. However, final rinsing must be done with great care to ensure that either rinse water or the rinsing operation does not result in recontamination of equipment and food contact surfaces. Where conditions are right, final disinfection without rinsing is recommended to take advantage of any residual or bacteriostatic effect of the disinfectant.

APPENDIX II

COMPARISON OF SANITIZERS

	Steam	Chlorine	Iodophor	Quat	Acid-Anionic
Equivalent strength (ppm)	--	200	50	200	100
Effective against Gram positive bacteria	Yes	Yes	Yes	Yes	Yes
Effective against Gram negative bacteria	Yes	Yes	Yes	Poorly	Yes
Effective against Listeria	Yes	Yes	Yes	Yes	Yes
Speed of Kill	Fast	Fast	Fast	Slower	Slower
Corrosive	No	Yes	Little	No	Little
Irritating to Skin	Yes	Yes	Variable	No	Yes
Affected by Soil	No	Most	Moderate	Little	Little
Affected by Hard Water	No	No	Little	Varies	Little
Deodorizing	No	Yes	Yes	Most	No
Active Residue	No	No	Yes	Yes	Yes
Test for Residue	No	No	Yes	Yes	Yes
Maximum level permitted without rinse (ppm)	--	200	25	200	*
Cost	High	Lowest	Low	High	High

* Sodium salt of oleic acid - 200 ppm
Dodecyl benzene sulfonate - 300 ppm

6. INVESTIGATIVE TECHNIQUES

INVESTIGATIONAL TECHNIQUES

A. Follow up to L. monocytogenes Contamination

Both the food industry and the regulatory agencies have a mutual concern and responsibility in investigating the incidence of bacterial pathogens in foods. Upon the isolation of Listeria monocytogenes from a ready-to-eat meat product during routine monitoring or consumer complaint activities, a follow-up investigation will be conducted. The investigation will focus on the process of the product in question, processing environment, and programmes/systems of control in place as they relate to control of L. monocytogenes.

B. Notification and Preparation for the Investigation

The manufacturer will be notified of the date of the investigation and should reserve that time accordingly. An effective investigation will require joint industry/regulatory agency co-operation to benefit from the special abilities and expertise which each can provide. This inspection team might be composed of representatives from the regional offices of the Health Protection Branch (Health and Welfare Canada) and the Food Production and Inspection Branch (Agriculture Canada), the resident inspection staff and company representatives.

A knowledge and understanding of process and product flows would greatly aid the assessment of the effectiveness of the manufacturer's product safety and quality programmes against L. monocytogenes. A manufacturer can best prepare by ensuring such information is available. (eg. floor plan layout, product flow diagrams, recall action plan, etc.)

C. Methodology and Areas of Concern

The investigation will focus on the process of the product in question and may include in-line and finished product analyses and environmental swabs for the presence of L. monocytogenes. The analytical methodology used by the Health Protection Branch is outlined in Section 7. An alternative sampling plan may be employed for investigations. Results of such analyses are used to supply additional information to the observations made during investigations. These analyses are not intended to replace the processor's responsibility of microbiological control on a day to day basis.

It is recognized that the potential for Listeria contamination will vary from one product to another, depending upon factors such as the raw materials, processing procedures, and the manner in which the product is marketed. It also may vary from one food processing plant to another producing the same product.

Good Manufacturing Practices applicable to all manufacturing operations were previously recommneded. Some areas of common concern which may be addressed during the investigation in an establishment include the following:

1. BACKGROUND INFORMATION

   - *L. monocytogenes* +ve product(s) identification and specific information (eg. trends) relating to the manufacture of the product in question.
   - lot number, date of manufacture, quantity, distribution.

2. PROCESSING INFORMATION

   - product formulation.
   - process flow and Hazard Analysis Critical Control Point considerations (eg. established Critical Control Points).

3. PROCESS CONTROLS

   - time-temperature relationships.
   - accuracy of measurements.
   - Critical Control Points monitored, records kept, contingency plans.
   - process validation.

4. CONSTRUCTION AND EQUIPMENT REVIEW

   - condensate and humidity control.
   - air movement, positive pressure in cooked area
   - GMP recommendations as previously outlined.

5. POST PROCESS CONTAMINATION

   - product flow, rework.
   - employee food handling, employee traffic.
   - employee hygiene.
   - packaging conditions.

6. CLEANING AND DISINFECTION

   - written schedule and procedures.
   - chemicals used, concentrations, temperatures, contact times.
   - environmental sanitation.
   - program validation.

7. QUALITY ASSURANCE PROGRAM

- raw materials specifications, contingency plans.
- finished product specifications, contingency plans.
- analysis conducted, *Listeria*.
- records kept (Critical Control Points, cleaning, maintenance, etc.).
- employee training programs, implementation.
- scheduled maintenance program, implementation.
- regular review/monitoring of cleaning and disinfection program.
- recall program.

D. *Post-Investigation Actions*

Upon completion of the investigation and analyses, the manufacturer will be given the investigational findings and the results of analyses in writing. A variety compliance actions based on violative findings may be initiated, however, most often a joint meeting of those involved in the investigation will be held to discuss these findings and the adequacy of the existing programs and systems of control in their ability to reduce the incidence of *L. monocytogenes* in the environment and finished product. It is the industry's responsibility to adjust, design and implement the programs to address *L. monocytogenes* in processing establishments. The manufacturer will be expected to provide their plan of action in writing to the regulatory agencies (Health and Welfare Canada, Agriculture Canada). Follow-up activities will assess the effectiveness of improvements by the manufacturer.

7. METHODS FOR ISOLATION

Laboratory Procedure

MFLP-60
December 1988

HEATH PROTECTION BRANCH

OTTAWA

ISOLATION AND IDENTIFICATION OF LISTERIA MONOCYTOGENES FROM MEAT

1. APPLICATION

This method is applicable to the enumeration of viable *Listeria monocytogenes* in foods to determine compliance with the requirements of Sections 4 and 7 of the Food and Drugs Act.

2. PRINCIPLE

This method is qualitative: As a portion of the product is taken through enrichment steps, plated on a specified agar medium, and incubated under specified conditions of time and temperature. It is assumed that each viable microorganism will multiply under these specified conditions of incubation and give rise to a visible colony which can be identified. This method is based on the method of McClain and Lee (8.12). Quantitative variations of this method, such as the direct plating method of Anders (8.9) and the MPN method (8.11), are included. Therefore it can also estimate the numbers of viable microorganisms per g or ml of product.

3. INTRODUCTION

Isolation of *Listeria monocytogenes* from meat is difficult and time consuming because of the variety of the competing bacterial organisms (usually with faster growth rates). Without the addition of an assortment of selective agents, and, as is always the case when selective agents are used, those *Listeria* cells that are injured may be susceptible to suppression by the inhibitor where the physiologically normal cell would not be. Bacteria present in almost all the meat and poultry samples examined in laboratories will have sustained some degree of damage from freezing and thawing; many will have sustained heat-damage and some will have been subject to injury from processes that include, but are not limited to, drying, and exposure to salt, acids and to spices with antimicrobial properties.

The selective enrichment media used are based on the medium of Ralovich *et al*. (8.1) who first used nalidixic acid to suppress non-listeric bacteria. This was adapted by Rodriguez *et al*. (8.2) whose medium was in turn modified by Donnelly and Baigent (8.3). It was selected for use in this procedure because *Listeria monocytogenes* had a shorter lag period in it than in several other selective broths and it was hoped that it would prove to be relatively less inhibitory to bacterial cells that might have sustained some degree of damage. In a step analogous to the two-stage enrichment procedure widely used for *Salmonella* isolation, the incubated original broth is transferred to a second enrichment broth that differs from the first only in the level of acriflavine that it contains. Competing bacteria may be further reduced in number by exposing the inoculum for the plating medium to potassium hydroxide, an idea originated by Lovett, Francis and Hunt (8.4) in the Food and Drug Administration. This step has been found to be ineffective and thus has been removed by HPB.

The formula for LPM plating medium is based on McBride medium (8.5), modified by others by substitution of glycine anhydride for glycine (8.6), and by Lee and McClain with the addition of the antibiotic Moxalactam and an increase in the concentration of lithium chloride to the level found in Baird-Parker medium (8.7). Between 50 and 100% of the colonies that grow on LPM agar will be members of the genus *Listeria* provided the two-stage enrichment and KOH treatment have been used. The procedures result in a method that is comparable to the best *Salmonella* isolation methods with respect to time and selectivity.

Although selective plating media suppress the growth of the competitive flora, there are likely to be bacteria that, using laboratory slang, we can call "sleepers" (contaminants in a bacterial colony whose growth is inhibited). Therefore it is necessary to purify isolants before proceeding with identification techniques.

This method is valuable for detection of surface contamination of raw and processed meat. It has also proven to be useful for detecting *Listeria* in the environment of the processing plant.

Isolation of *Listeria monocytogenes* using enrichment techniques attests to its presence in a food but says nothing about any attendant dangers to the one who eats it. The organism is widespread in nature, especially in plant material, and the bodily defenses against it are evidently strong. The cell walls contain a powerful stimulator of the immune system, and at present it seems likely that exposure to this organism is fairly steady over a lifetime and that the population as a whole is protected by "natural resistance". The aged, whose immunity is waning; the unborn and newborn, whose immune systems are not fully developed; the immuno-compromised, and the pregnant are especially susceptible to this bacterium and, for this group, mortality is high. There remain some infections in individuals that cannot be assigned to any of the aforementioned groups and it seems likely that such persons have been exposed to numbers of the bacteria that overwhelm the natural defenses. The infectious dose for normal persons is not known.

Like the lactic acid bacteria, listeriae can grow in the cold. At 4°C the generation time is 1.5 days in milk according to Doyle (8.8). Therefore it is obvious that *Listeria monocytogenes* is not controlled by conditions, the bacteria can grow and might even flourish before the shelf-life has expired. It is inevitable that enumeration will be attempted on occasion as circumstances dictate. In an addendum to this method some suggestions for enumeration are offered, but with the cautionary statement that, as of this date, enumeration has not been thoroughly studied.

4. DEFINITION OF TERMS

4.1 Lot: A batch or production unit which may be identified by the same code. When there is no code identification, a lot may be considered as (a) that quantity of product produced under essentially the same conditions, at the same establishment and representing no more than one day's production; or, (b) the quantity of the same kind of product from one and the same manufacturer available for sampling at a fixed location.

4.2 Sample: The sample units (subsamples) taken per lot for analysis.

4.3 Sample Unit: Usually a consumer size container of the product, and should consist of a minimum of 100 g (ml). A sample unit is often referred to as a subsample.

4.4 Analytical Unit: It is that amount of product withdrawn from the sample unit for analysis.

5. COLLECTION OF SAMPLES

5.1 A sample, consisting of five sample units drawn at random from each lot, shall be taken. The number of sample units will depend in part upon the nature of the product. This sampling scheme is to be followed unless otherwise stipulated via Table 1.

5.2 Each sample unit shall contain at least 100 g or ml.

5.3 Collect original unopened containers wherever possible.

5.4 If the product is in bulk, several sample units can be collected from one container, while ensuring that the total number of sample units are not collected from one container.

More than one sample unit may also be collected from large institutional or bulk containers when the total number of sample units required exceeds the number of containers in the lot. Place the collected sample units in sterile containers. A sample unit will consists of more than one container when the lot consist of containers smaller than 100 g, e.g., four 25 g containers in each sample unit.

5.5 Employ aseptic techniques in collecting the sample units when sampling from bulk. Place them in separate sterile containers.

5.6 During storage and transport, the following shall apply: with the exception of shelf-stable products, keep the sample units refrigerated (0-5°C). Analyze within 3 days of sampling. Sample units of frozen products shall be kept frozen.

6. PROCEDURE

Analyze each sample unit individually. Or take a 25 g analytical unit from each sample unit (5 x 25 g) and composite for analysis. See Table 1. Additional information on *Listeria* distribution will be obtained by analyzing each sample unit.

The test shall be carried out in accordance with the following instructions:

6.1 Handling of Sample Units

6.1.1 As for 5.6.

6.1.2 Analyze sample units as soon as possible after receipt in the laboratory.

6.2 Material and Equipment

See Section 7.

6.3 Enrichment and Plating

Weigh a 25 g analytical unit (or 5 x 25 g) into a blender. Add 225 ml (or 5 x 225 ml) of *Listeria* enrichment broth (LEB). Blend 2 minutes. Incubate the blender jar overnight at 30°C.

Alternately, if the entire sample is to be analysed, the sample instead may be minced and processed in a STOMACHER for 2 minutes. Twist and tie the bag about 1/4 of the distance from the top. Incubate overnight at 30°C.

Secondary enrichment: Transfer 0.1 ml of the incubated broth to LEB #2. Incubate at 30°C overnight.

Streak an LPM agar plate from the incubated LEB #2 (fig. 4). Incubate both plates at 30°C overnight.

6.4 Examination of Incubated LPM Agar Plates

It is necessary to examine LPM agar plates by 45° transillumination (Henry illumination) to detect *Listeria* colonies. Please refer to fig 1, fig 2 and fig 3 for the placement of the microscope and lamp. Colonies of *Listeria monocytogenes* are sparkling blue or white under 45°C transillumination; the size varies.

6.5 Colony Selection and Restreaking

Gently touch 5 colonies suspected of being *Listeria* in succession with the inoculation needle. Streak for isolation onto a horse blood overlay agar plate. Then with the loop, take a sweep of the LPM plate and streak for isolated colonies on another horse blood overlay agar plate. Do this at least twice. This should be done for each plate inoculated the previous day.

Note: When there is no isolated colonies on the LPM plates, do the sweeps and streaking on the blood plate a minimum of twice. This should be done for each plate inoculated the previous day.

Because the plates are so thin they are easily scratched and should be streaked with a thin, flexible platinum wire. Incubate overnight at 35°C.

6.6 Examination of Incubated Horse Blood Overlay Agar Plates

Examine the plates with a strong light. Hold the plate at a right angle to a fluorescent lamp and view the bottom of the plate (fig 5). Select translucent colonies, about 2 mm in diameter, with a narrow zone of beta hemolysis surrounding the colony and complete clearing of the blood underneath.

THIN PLATES AND STRONG LIGHT ARE NEEDED TO DEMONSTRATE BETA HEMOLYSIS BY SURFACE COLONIES OF *Listeria monocytogenes* prepared as stated; it is more easily demonstrated with subsurface growth on pour plates or when streaked growth has been stabbed into the agar. Incubation of the plates in an atmosphere of 2-5% CO_2 intensifies the hemolytic reaction.

6.7 Screening

Colonies suspected of being *Listeria monocytogenes* are picked with a needle and transferred to motility medium (by stabbing) and to BHI. Incubate at 20-25°C.
After overnight incubation, examine BHI broth by wet mount or hanging drop for tumbling motility; also make a gram stain.

Incubate the motility medium for 2 or more days. Observe for an umbrella type of growth (fig 6) which is typical of *Listeria monocytogenes*. Discard tubes which lack this appearance.

NOTE: Proceed with identification tests only if the culture is gram-positive, has tumbling motility, and appears to be smooth.

6.8 Identification and Confirmation Tests

Follow the *Manual of Clinical Microbiology* (8.6) or *Bergey's Manual of Determinative Bacteriology* (8.13) for identification of the genus *Listeria* and confirmation of the species *monocytogenes*.

Media used in the identification and confirmation of *Listeria monocytogenes* can be inoculated from the BHI broth. Inoculate a slant of BHI agar to be used for the catalase and oxidase tests. Also inoculate spore medium, bile esculin agar, MR/VP medium, O/F medium, nitrate broth, and rhamnose, xylose, and mannitol fermentation broths.

CAMP TEST*: Streak OVERNIGHT BHI broth cultures of *Staphylococcus aureus*, ATCC 25923 and *Rhodococcus equi*, on a plate of the sheep blood agar. Streak suspected listeriae at a 90° angle (fig 7). Incubate the plates at 25°C for 2-3 days. A positive reaction is a rectangular-shape hemolytic zone close to the staphylococcal or rhodococcal growth. *L. seeligeri* reacts the same way but differs in other characteristics.

Listeria monocytogenes is a gram-positive, non-sporeforming short rod that exhibits tumbling motility at 25°C. It is beta-hemolytic and gives a positive CAMP test with *S. aureus*, but not *R. equi* on sheep blood agar. It is catalase positive, oxidase negative, MR and VP positive, bile esculin positive, fermentative with respect to glucose, does not reduce nitrate, ferments rhamnose and fails to ferment xylose and mannitol.

---

* CAMP TEST cultures of *Staphylococcus* and *Rhodococcus* are available from Dr. Jeff Farber, Research Division, Bureau of Microbial Hazards, 4th Floor, Sir Frederick Banting Research Center, Ottawa, Ontario, K1A 0L2.

6.9 Suggestions for Enumeration

6.9.1 Direct Plating

6.9.1.1 Anders Method (8.9)

1. Make a 1:5 homogenate of meat sample in LEB.

2. Incubate for 3-4 hours to allow for recovery of injured cells.

3. Spread 0.2-0.4 ml of the homogenate evenly on an LPM agar plate with a glass hockey stick. Do not push all the meat debris to the edge of the plate because most of the colonies that develop are associated with the particles.

4. Incubate the plates in a plastic bag at 30°C. Look at the plates daily for 4 or 5 days.

6.9.2 MPN Method

Blend samples in LEB. Dispense aliquots following customary MPN procedures. Incubate as usual and follow the regular procedure already given with each aliquot. Estimate numbers with the appropriate 3-tube or 5-tube MPN table.

7. MATERIAL AND EQUIPMENT

7.1 Optical Requirements

A brightfield, darkfield or phase contrast microscope for observation of tumbling motility.

Microscope and lamp assembly to achieve 45°C angular illumination. This can be achieved with a dissecting microscope by using a light source and a mirror (fig. 1) or with an inverted microscope and a light source (fig. 2).

If there is one step in the Listeria isolation procedure that presents a problem for the inexperienced, it is the selection of colonies from agar plates. Bacteriologists around the world, who are experienced with Listeria, use and recommend Henry's 45°C illumination technique (fig. 3). This uses a dissecting microscope, plane mirror and microscope lamp all arranged such that the light strikes the colonies on the petri dish at the required angle. The colonies are seen to be blue or blue-green when illuminated by oblique light.

The FSIS Food Microbiology Laboratory in Beltsville substitutes a concave mirror, in place of the plane mirror, with the dissecting microscope assembly following a suggestion of Hayes et al. (8.14). The glass stage of the dissecting microscope was removed and replaced with PLEXIGLASS 1/8" thick.

USE OF A PLATED OVERNIGHT CULTURE OF Listeria monocytogenes IS RECOMMENDED FOR CHECKING THE ALIGNMENT OF THE MICROSCOPE EACH DAY THAT COLONIES WILL BE PICKED FROM PLATES.

7.2 Media

7.2.1 Listeria enrichment broth (LEB) alias UVM* (8.3)

* (There is more than one formula with the same name. This particular medium was developed by Donnelly and Baigent at the University of Vermont; hence U, and VM for Vert Mont, the Green Mountain State).

Proteose peptone	5 g
Tryptone	5 g
Lab lemco powder (OXOID)	5 g
Yeast extract	5 g
NaCl	20 g
KH_2PO_4	1.35 g
Na_2HPO_4	12 g
Esculin	1 g
**Nalidixic Acid (2% in 0.1M NaOH)	1 ml
Distilled water	1 L

** (Please note that the amount of nalidixic acid given here is 1/2 the amount given in the original formula),

Sterilize at 121°C, 15 minutes. DO NOT OVERHEAT; COOL AT ONCE AFTER REMOVAL FROM THE STERILIZER. Store in the refrigerator. JUST BEFORE USE, ADD 1.0 ml OF 1.2% FILTER-STERILIZED ACRIFLAVINE.

7.2.2 LEB # 2

This broth is identical in formula to that above except for increased acriflavin.

Put 10 ml of *Listeria* Enrichment Broth (LEB) into 20 x 150 mm screw cap tubes and sterilize at 121°C, 15 minutes. OBSERVE CAUTIONARY STATEMENT ABOUT OVERHEATING AND COOLING. JUST BEFORE USE, ADD 0.1 ml OF 2.5 mg/ml FILTER-STERILIZED ACRIFLAVINE.

7.2.3 LPM Plating Medium (8.6)

Basal agar:

Phenylethanol agar (DIFCO)	35.5 g
Glycine anhydride	10 g
LiCl	5 g
Distilled water	1 L

MOXALACTAM Solution:

Sodium (or ammonium) MOXALACTAM (LILLY)	1 g
0.1 M potassium phosphate buffer (pH 6)	100 ml

Sterilize by filtration. Dispense in 2 ml quantities and keep in freezer.

Sterilize the basal medium at 121°C, 12 minutes. Cool to 46°C. Add 2 ml of 1% moxalactam. Stir with a magnetic mixer and dispense 12 ml per 100 mm petri dish.** Refrigerate plates. THE BASAL MEDIUM CANNOT BE MADE IN ADVANCE AND REHEATED.

* DO NOT SUBSTITUTE GLYCINE FOR GLYCINE ANHYDRIDE.
** IT IS CRITICAL THAT THE PLATES BE THIN.

7.2.4 Horse Blood Overlay Medium (8.6)

7.2.4.1 Base Layer

Columbia CNA blood agar base (DIFCO)	44 g
Distilled water	1 L

Sterilize at 121°C for 15 minutes. Pour 10 ml per 100 mm diameter petri dish. Allow to solidify and while still warm, overlay with blood agar.

7.2.4.2 Top Layer

Add 4% horse blood to melted Columbia CNA **blood agar** base, which has been cooled to 46°C. Stir or swirl to **mix** evenly. Put 5 or 6 ml on top of the base layer **and tilt the plates** to spread the top layer evenly. Store plates **in the refrigerator**. Discard any discolored plates. THIN PLATES ARE NECESSARY TO DEMONSTRATE LISTERIAL BETA-HEMOLYSIS BY SURFACE COLONIES.

7.2.5 Camp Test Agar

Trypticase soy agar containing 5% sheep blood. Pour 8 ml per 100 mm diameter petri dish. Store plates in the refrigerator. Discard any discolored plates.

7.2.6 Sporulation Agar

Nutrient agar containing 1 ml per liter of a 3.08% solution of MnSO4.

7.3 Carbohydrate Fermentation Broth

7.3.1 Base

Peptone	10 g
Lab lemco powder (OXOID)	1 g
NaCl	5 g
Distilled water	900 ml
Phenol red (360 mg/20 ml 0.1 N NaOH)	1 ml

Adjust pH to 7.4 and sterilize at 121°C for 15 min.

7.3.2 To the cooled basal fermentation broth, add 100 ml of a filter-sterilized carbohydrate as indicated below.

Xylose, 5%
Mannitol, 10%
Rhamnose, 5%

Dispense aseptically: 5 ml per 13 x 100 mm sterile screw cap tube.

7.4 The following media are obtainable in dehydrated form and are made as per manufacturer's directions:

MOTILITY AGAR (DIFCO) Dispense 4 ml per 13 x 100 mm tubes
BRAIN HEART INFUSION BROTH (BHI)
BRAIN HEART INFUSION AGAR SLANTS
BILE ESCULIN AGAR SLANTS
GLUCOSE BROTH (MR/VP)
OXIDATION/FERMENTATION MEDIUM (O/F)

NITRATE BROTH
OXIDASE TEST REAGENT (1% tetramethyl-p-phenylenediamine dihydrochloride)

THE MEDIA CONTAINED IN THIS SECTION ARE, ON THE WHOLE, HEAT-SENSITIVE, AND IT IS IMPORTANT TO OBSERVE THE TIMES AND TEMPERATURES GIVEN FOR THEIR PREPARATION. LEFT-OVER, UNPOURED AGAR SHOULD BE DISCARDED.

8. REFERENCES

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TABLE 1. The Sampling Scheme for Ready-to-eat Foods being Analyzed for L. Monocytogenes

Food Product	Sampling	Analysis
1. Foods causally linked with listeriosis (soft cheese, fluid milk, coleslaw) pH > 5.0, a_w > 0.95	5 sample units (100 g or ml each) taken at random from each lot.	5x25 g analytical units are either analyzed separately or composited.
2. Other dairy products, not causally linked, but supporting growth a) frozen (e.g., ice cream) b) refrigerated (e.g., semi-soft cheese) c) held at ambient temperatures (e.g., process cheese)	5 sample units (100 g or ml each) taken at random from each lot.	a) 5x10 g b) 5x25 g c) 5x25 g analytical units are either analyzed separately or composited.
3. Other dairy products, not causally linked, and not supporting growth a) refrigerated (e.g., hard cheese) - pH ≤5.5 and a_w ≤0.95 - pH ≤5.0 even though a_w >0.95 - pH >5.5 but a_w ≤ 0.92 b) held at ambient temp. (e.g., grated Parmesan cheese)	5 sample units (100 g or ml each) taken at random from each lot or 2 sample units ("plugs" of at least 25 g) from each of 2 whole wheels taken at random from the lot.	a) 5x10 g or 2x25 g analytical units for whole wheels b) 5x5 g analytical units are either analyzed separately or composited.
4. Other foods permitting growth, but not causally linked, either frozen or refrigerated (e.g., precooked shrimp, lobster, crab, bologna, roast beef)	5 sample units (100 g or ml each) taken at random from each lot.	5x10 g analytical units are either analyzed separately or composited.
5. Other foods not causally linked and not supporting growth (e.g., jerky, dry salami, dried salted fish, raw whole vegetables, fruit, stored cereal products).	5 sample units (100 g or ml each) taken at random from the lot.	5x5 g analytical units are either analyzed separately or composited.

Fig 1 Dissecting Microscope, Lamp and Mirror (8.11)

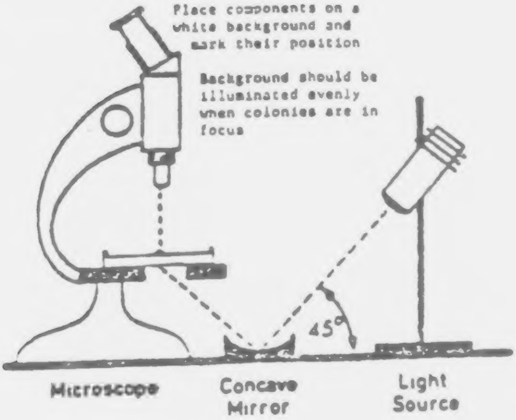

Place components on a white background and mark their position
Background should be illuminated evenly when colonies are in focus
45°
Microscope
Concave Mirror
Light Source

Fig 2 Inverted Microscope and Lamp (8.11)

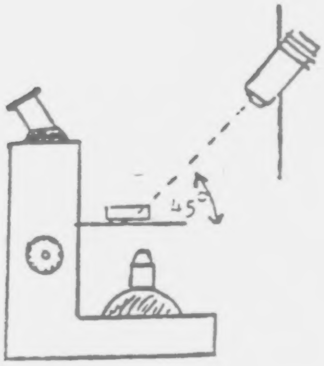


Fig 3 Examination of plates for suspect colonies (8.12)

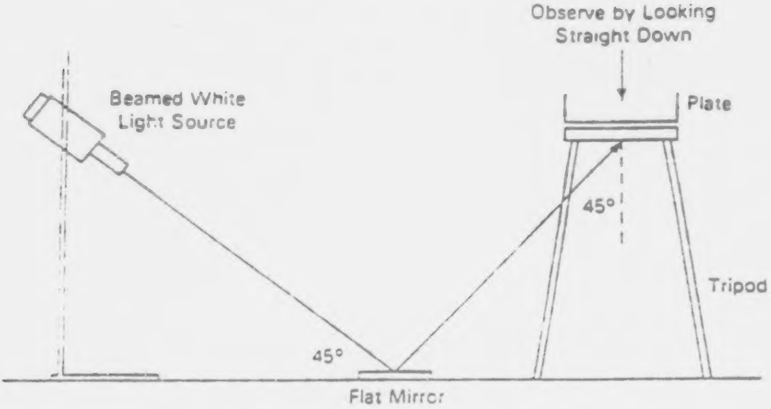

Observe by Looking Straight Down
Beamed White Light Source
Plate
45°
Tripod
45°
Flat Mirror

Fig 4 Streaking pattern for LEB #2 (8.11)

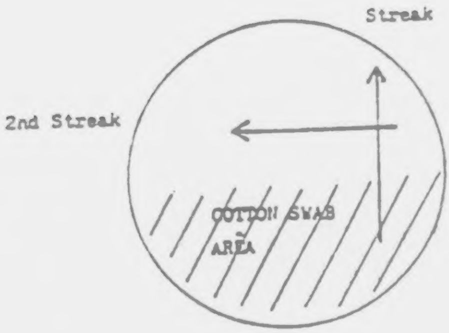

Streak
2nd Streak
COTTON SWAB AREA

Fig 5 Viewing angle for horse blood overlay plates (8.11)

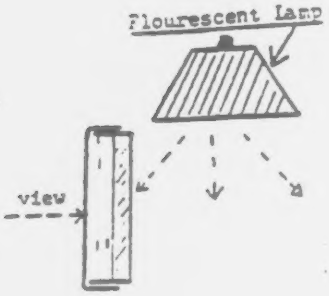

Flourescent Lamp
view

Fig 6 Umbrella motility (8.11)

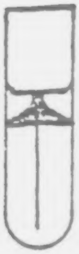
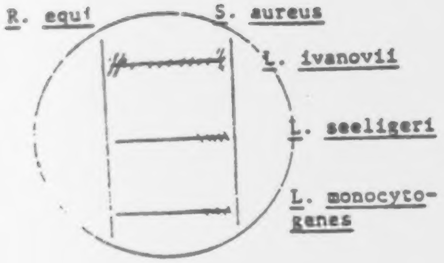


Fig 7 Camp Test (8.11)


R. equi
S. aureus
L. ivanovii
L. seeligeri
L. monocytogenes

8. ENVIRONMENTAL SAMPLING

ENVIRONMENTAL SAMPLING

An environmental sampling program is a means of verification available to the manufacturer, which will validate that the systems in place, (GMPs), are effective in maintaining a plant environment that will minimize the hazard of *Listeria monocytogenes* contamination of the finished products. The detection of pathogenic microorganisms in the environment is a qualitative procedure (presence or absence, not #/area), and it can:

- Demonstrate the effectiveness of the sanitation program with respect to *Listeria monocytogenes*
- Identify probable post-processing cross-contamination sites
- Identify the extent of *Listeria monocytogenes* contamination (% of total samples which are positive)
- Allow the manufacturer to assess the likelihood of finished product contamination from *Listeria monocytogenes* positive environmental sites and initiate appropriate corrective actions
- Provide information on faulty equipment design and operation

1. SELECTION OF SITES FOR ENVIRONMENTAL SAMPLING

Deciding where to sample in order to get the most from an environmental sampling program is as important as good sampling techniques. A systematic method of deciding where to sample involves reviewing the process flow and identifying potential sites of post-processing cross-contamination. Where products are handled or further processed after cooking/ processing, sanitation of the environment is a critical control point.

Emphasis on environmental sampling should be given to product contact surfaces in the finished product area:

- All surfaces which directly contact the finished product (eg. slicers, tables, employees hands/gloves, etc.)
- Surfaces from which liquids may drain, drop or be drawn into the finished product or finished product container (eg. condensate laden piping, conveyors, etc.)
- Surfaces or items that may touch surfaces which directly contact finished products (eg. mops/cleaning aids, aprons, etc.)

Within each area, those surfaces most apt to be conducive to the harbourage and growth of *Listeria monocytogenes*, ie. sites where water, food debris may accumulate or become trapped, should be swabbed (eg. dented surfaces, dead spots, etc.). Non-product contact surfaces (all other surfaces) may be sampled to more clearly define the problem area.

Examples of process flow charts for cooked and fermented products, along with their critical control points are given in Appendix A and Appendix B. These examples are for your guidance only. Depending on the product, the process, and the unique characteristics of each individual plant, there will probably be several sites where post-processing contamination could take place. Ten to twenty samples are usually sufficient.

2. SAMPLING TECHNIQUES

2.1 Records

After a site has been selected, a record must be made identifying the site selected and the visual condition observed at the swabbing site. Record keeping is important, as environmental sampling is of retrospective value only, ie. results may be received long after products have been distributed. The manufacturer must know in addition to the exact location, the conditions (ie. food debris, condensate) under which a positive is obtained in order to implement appropriate corrective actions.

2.2 Time of Sampling

Sampling should be done in the latter part of a shift so as to collect as much information as possible on the operational procedures and the effectiveness of the *Listeria* control program within the plant. On occasion, the swabs could be taken immediately after cleaning and sanitizing, and before production, to assess the effectiveness of the sanitation program with respect to *Listeria monocytogenes*.

2.3 Size of Sample

As swabbing is done to detect the presence or absence of *Listeria monocytogenes* in the environment, the sampling site should be as large as practical but should still delineate a distinct area of concern. Areas of up to 1 m^2 may be swabbed, however, areas of 1 ft^2 can give good results if proper techniques are used.

2.4 Aseptic Sampling

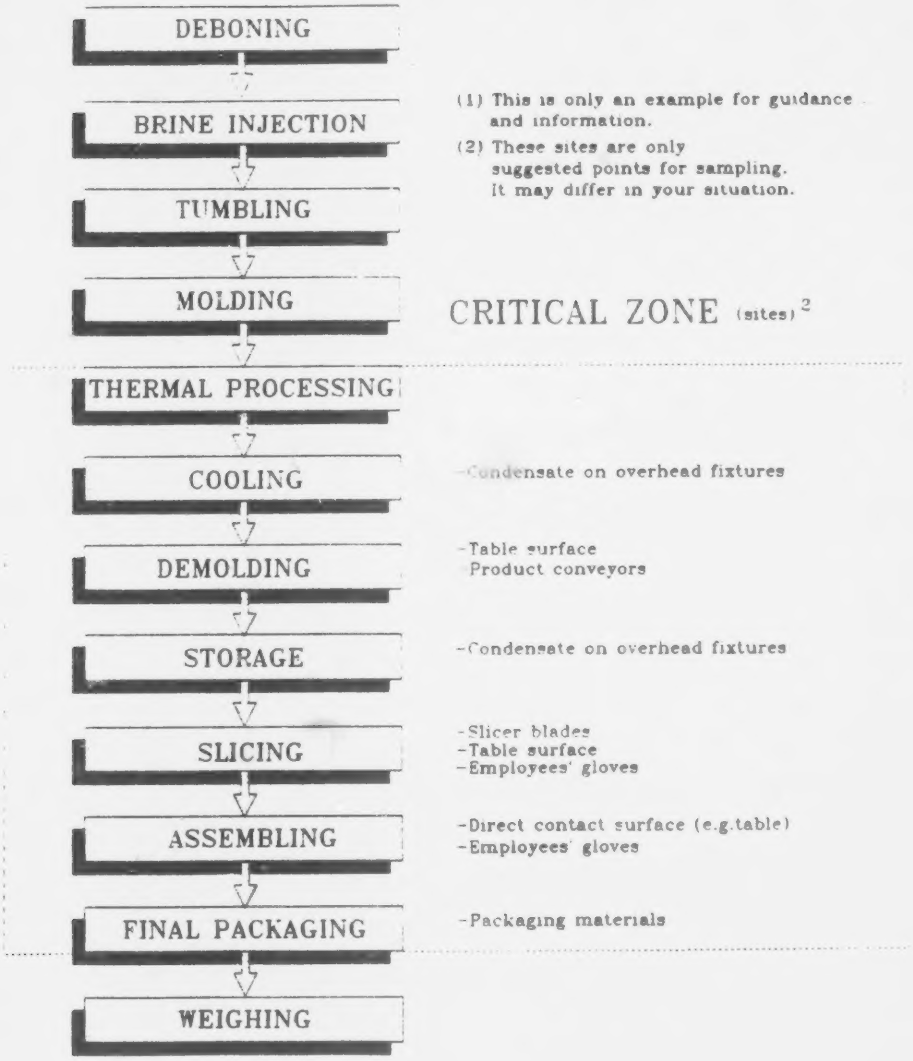
A new pair of sterile gloves should be worn and discarded, or separate sterile forceps should be used for each sample collected. Whichever method is used, care should be taken so as not to contaminate the swab during handling. It is also recommended to start from the cleanest area and work toward dirtier areas. The swab (sponge) is removed from its container, and if not already impregnated with enrichment broth, is moistened with diluent as supplied. The swab is obtained by vigorously rubbing the sponge over the selected area until visibly soiled. Carefully place the sponge in a sterile plastic jar or bag and label the container for identification. The site that has been sampled may then be sprayed/wiped with a solution of 200 ppm chlorine to denature media and sanitize the swabbed area. Note that the swabs (sponges) can be placed directly into a selective Listeria enrichment broth (LEB (UVM)#1) at the processing plant.

2.5 Storage

The swabs (sponges) should be stored and transported to the laboratory under refrigeration within 24 hours or as soon as possible. The laboratory should then proceed as per instructions in Health Protection Branch method MFLP-60 (see section 7).

Appendix (A)

Cooked / Sliced Ham[1]


DEBONING
BRINE INJECTION
TUMBLING
MOLDING
THERMAL PROCESSING
COOLING
DEMOLDING
STORAGE
SLICING
ASSEMBLING
FINAL PACKAGING
WEIGHING

(1) This is only an example for guidance and information.

(2) These sites are only suggested points for sampling. It may differ in your situation.

CRITICAL ZONE (sites)[2]

COOLING:
-Condensate on overhead fixtures

DEMOLDING:
-Table surface
Product conveyors

STORAGE:
-Condensate on overhead fixtures

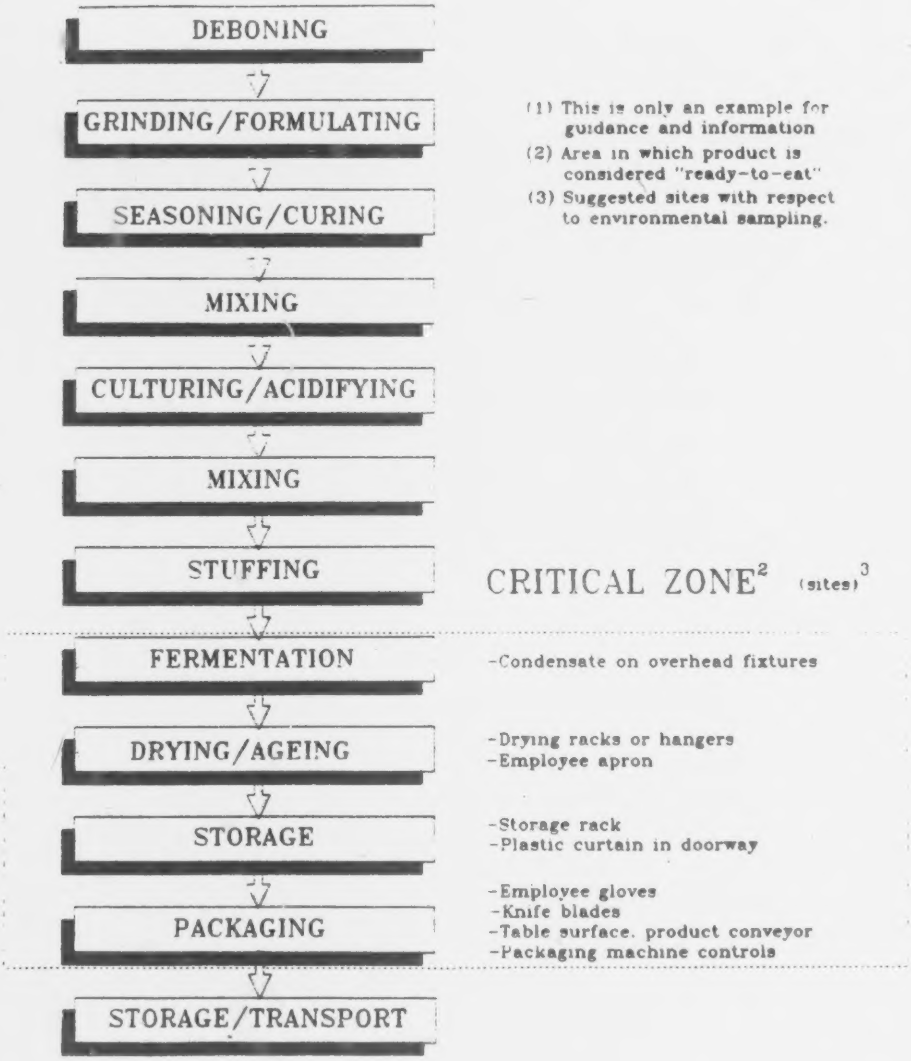
SLICING:
-Slicer blades
-Table surface
-Employees' gloves

ASSEMBLING:
-Direct contact surface (e.g.table)
-Employees' gloves

FINAL PACKAGING:
-Packaging materials

Appendix (B)

Fermented Meats[1]


DEBONING
GRINDING/FORMULATING
SEASONING/CURING
MIXING
CULTURING/ACIDIFYING
MIXING
STUFFING
FERMENTATION
DRYING/AGEING
STORAGE
PACKAGING
STORAGE/TRANSPORT

CRITICAL ZONE[2] (sites)[3]

- -Condensate on overhead fixtures
- -Drying racks or hangers
- -Employee apron
- -Storage rack
- -Plastic curtain in doorway
- -Employee gloves
- -Knife blades
- -Table surface, product conveyor
- -Packaging machine controls

(1) This is only an example for guidance and information

(2) Area in which product is considered "ready-to-eat"

(3) Suggested sites with respect to environmental sampling.

ATTACHMENT G

3/12/90

Dr. A. Gravel, Director
Meat and Poultry Products Division
Agriculture Canada
2255 Carling Avenue
Ottawa, Ontario K1A 0Y9

Dear Dr. Gravel:

This responds to your providing FSIS with documents detailing Canadian controls on *Listeria monocytogenes.* The enclosed comments have been prepared in our Science Program.

I hope this information is useful.

Sincerely,

/s/

Patricia Stolfa
Deputy Administrator
International Programs

Enclosure

Forwarded, Foreign Agricultural Service

cc:
Minister-Counselor, American Embassy, Ottawa
FAS/AO

Subject: Canadian Listeria Control Program

I have reviewed the subject book and have the following response to your questions.

POINT BY POINT COMPARISON OF U.S. AND CANADA PROGRAMS

Section 1. Introduction and Definition

Joint action is undertaken by Ag Canada and Health and Welfare Canada. While FSIS and FDA have held meetings, a similar but not a joint approach is taken.

- The book is not dated so we have no way of knowing when it was issued. We assume that its recent.
- Control is limited to Listeria monocytogenes the same as it is in FSIS.

Section 2. Fact Sheet

The facts presented are essentially the same as those used by FSIS. One exception is the 39% prevalence figure for Lm in ready-to-eat products. In the U.S., the prevalence is approximately 3% for freshly produced meat and poultry products.

Section 3. Policy and Implications of Contamination

For the most part, Section 3 is very similar to the FSIS policy, however, there are some important differences.

- Canada stresses that the foods associated with listeriosis have been those with high numbers, and states that there is little evidence that low numbers of *L. monocytogenes* in a food will cause listeriosis, even in susceptible individuals.

  While low and high levels are not defined, an illness in a susceptible individual from a cooked turkey frank in the U.S. was reported. The number of *Listeria monocytogenes* in the remaining franks from the home was estimated to be approximately 1,000. Since this was before cooking, the cell level of the cooked frank may have been in the "low" range.

- Canada classifies food containing *L. monocytogenes* by category of risk as follows:

  1. Dairy products which will support growth of *L. monocytogenes* (milk, soft cheeses, etc.).

  2. Dairy products which do not support growth. (Hard cheese, ice cream, etc.).

  3. Any ready-to-eat food other than 1 and 2 which will support growth. (Lunch meat, etc.).

  4. Any ready-to-eat food other than 1 and 2 which will not support growth (Dried meat, fermented sausage, etc.).

  5. Any product that is epidemiologically linked to an outbreak of listeriosis.

  The Canadian risk classification system is used to trigger different levels of compliance action such as class of recall and public notification.

  The U.S. policy differs for meat and poultry in that we do not establish hazards by assumed food risks. The compliance action for all product categories other than raw products is the same. In addition, the FDA policy for foods, that they regulate, is essentially the same as that of FSIS.

Section 4. Good Manufacturing Practices

This section provides very good, lengthy descriptions of Good Manufacturing Practices in addition to descriptions of HACCP controls and a recommended recall plan. The intended purpose of this section is to provide control procedures for the food industry.

In the U.S., similar information is available in FSIS directives, fact sheets, copies of speeches, training materials, etc. In addition, trade groups such as the American Meat Institute have disseminated industry GMPs and HACCP information. Much of this was used and is referenced in this section.

Section 5. Clean-up Protocol

The information presented is very similar to that available from multiple sources in the U.S. Note that all five references originated in the U.S.

Section 6. Investigational Techniques

What is done in Canada as a consequence of a positive Listeria monocytogenes in an establishment's product, is similar to what is done in the U.S. under such circumstances. There are differences in who does it, the responsibilities for doing it and the compliance actions.

- Canada sends a team of two agencies in to work with company representatives. In the U.S., representatives of CDC are not part of the team unless illness is linked to the firms product. In addition, the primary responsibility for correction of defects rests with the company affected.

- The Canadian team takes product and environmental samples.

  In the U.S., the product line in question is shut down and the clean up and correction of defects is the responsibility of the company with some input from the resident inspector and the Regional Office. FSIS does not collect product and environmental samples since we stop the production. The company may sample to aid them in locating and correcting the problem(s).

Patricia Stolfa

- o Canada states that a variety of compliance actions "may" be taken as a consequence of the findings of the investigational team.

  In the U.S., the compliance actions are spelled out and are standardized. The lot with the monitoring positive will be recalled if in commerce and condemned or reprocessed if voluntarily held. In addition, new production of the incriminated product will be held and tested until five consecutive lots are found to be free of contamination.

Section 7. Method for Isolation

As stated in the second paragraph, this method is based on the method of McClain and Lee of the FSIS Beltsville Laboratory. Therefore, the method is nearly identical to the FSIS method. There is a difference in sampling. Canada takes five samples and tests 25 grams from each. FSIS takes six samples and tests a 25 gram sample from five of these (5 grams from each). The sixth sample is stored intact at 40°F until the end of declared shelf life, or 70 days if not declared, then 25 grams of this are tested.

Section 8. Environmental Sampling

It appears that the Canadian government collects and tests environmental samples routinely. In the U.S., this is not routinely done, it is done by some corporations. One exception is that it will be done if illness is associated with the product.

PUBLIC HEALTH DIFFERENCES BETWEEN THE TWO PROGRAMS

It is well recognized that it will take years to control Listeria to the near no defect level. I believe that this is recognized by Canada just as we recognize it in the U.S. The Canadian program is clearly an aggressive preventive one and I characterize the U.S. program in the same terms. While there are some areas in the Canadian program that are stronger than ours, the reverse is also true. In my judgement, I feel that both of the programs are equal in their overall intent and effort. Both are initiating a level of sanitary control by establishments that has never before been deemed necessary. This effort has a cumulative effect for other bacteria of public health concern thus Listeria programs in both countries yield an unrecognized, significant public health bonus. With this in mind, the differences between the Canadian and U.S. Listeria programs are of almost no significance.

WILL FSIS MOVE TOWARD THE CANADIAN LISTERIA PROGRAM

Overall, I believe that the two programs accomplish the same objective but there are some differences in who does it. In the Canadian program, we see the industry, Canada Ag and the Health Protection Branch forming teams to review all firms found to have positive products. This is akin to forming industry, CDC, FDA and FSIS teams in the U.S. to investigate positive plants. Its an excellent concept although it is expensive and probably reflects differences in regulations. Without legislative changes, it is unlikely that the U.S. will move in this direction for routine positive incidents. Where human illness is a factor, we have coordinated plant investigations with CDC but not FDA.

o Environmental samples:

In contrast to Canada, environmental sampling is conducted by industry as part of their GMP except in the case of associated illness. It is not too likely that FSIS will assume the testing of environmental samples. This could change somewhat in the distant future if the HACCP system becomes incorporated in new regulations. Even if such a regulation change is made, environmental sample testing would likely be conducted by industry not FSIS.

o CATEGORIZING LISTERIA RISK ON THE BASIS OF WHETHER FOODS CAN SUPPORT GROWTH OR NOT

While there is some basis to categorize the degree of risk by food products, it is tricky to do and lacks scientific agreement. Future research and epidemiology will better define the validity of this issue but at this time FSIS is more comfortable without multiple categories. One aspect of Canada's classification program appears to include market recalls without public notification. This is a very controversial action in the U.S. and seldom, if ever, practiced in the U.S. where health risks are involved.

- Infectious Dose: This issue is probably the most controversial of all those associated with *Listeria monocytogenes*. Most of the population can ingest very high numbers of the microorganisms without effect, a smaller segment of the population can become seriously ill by ingesting low numbers. A very disturbing aspect of those that are ill is the associated 30-40% mortality. Not only do we need much more information on the infective dose but we need it in multiple segments of the population. It is unlikely that such information can ever be attained. Rather than concentrate concerns on a floating infectious dose, both the U.S. and Canada hold the position that processing and sanitation controls must be improved to minimize the microorganism to some level. This is not zero as often stated. In the U.S., the judgement is none in 25 grams. In Canada, its none in 125 grams. While there appears to be a disparity here, it is eliminated by the shelf life sample of an intact unit in the U.S. This may be 2 ounces or 2 pounds. Regardless, it is an excellent, highly sensitive test to challenge the process and packaging control. Therefore, in my judgement, the two programs are equal with one exception.

  The loose leaf book prepared by Canada is exceptional. It is comprehensive, outlined clearly, impeccably accurate and very impressive. More importantly, the information is targeted for the people who can make the needed changes, the industry, regulatory inspectors and officials and public heath officials. This information is generally available in the U.S. but is not compiled as it is in this book. I think FSIS will have to consider preparing such a compilation.

Question 7. Are any steps being taken to remove these differences?

Response. As mentioned above, FSIS has written to Agriculture Canada on this matter, and is awaiting its response. In the meantime, FSIS POE testing is presently in place to detect noncomplying product.

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